REDACTED

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: JAMES MARINO, M.D. Physician's and Surgeon's Certificate No. G 40978 Respondent.	Case Nos. 10-2002-141437; 10-2002-133773; 10-2003-153599 OAH No. L2005060740

DECISION AFTER RECONSIDERATION

This matter came regularly for hearing before James Ahler, Administrative Law Judge, Office of Administrative Hearings, State of California, on April 4-7 and 10-12, 2006, in San Diego, California. Steven H. Zeigen, Deputy Attorney General, represented complainant David T. Thornton, the Executive Director of the Medical Board of California, State of California. Michael J. Grace, Attorney at Law, represented respondent James Marino, M.D., who was present throughout the administrative proceeding. Oral and documentary evidence was presented and on April 12, 2006, the matter was submitted.

The Administrative Law Judge issued his Proposed Decision on May 11, 2006, and the Division of Medical Quality (Division) adopted the Decision on June 7, 2006 to become effective on July 7, 2006. Deputy Attorney Zeigen timely filed a petition for reconsideration. The Division issued an Order Granting Reconsideration on June 28, 2006 and stayed the effective date of the Decision until the Board issued its decision after reconsideration.

On November 2, 2006, the Division heard oral argument on the matter and written argument on reconsideration was filed by both parties. Having reviewed the record, the petition for reconsideration, and other documents submitted by the parties, the Division now makes and enters its decision after reconsideration as follows:

ISSUES

Between June 2000 and February 2001, did Dr. Marino engage in gross negligence, repeated negligent acts, or demonstrate incompetence in connection with his care and treatment of three orthopedic patients?

If so, does cause exist to impose license discipline?

If so, what measure of license discipline should be imposed to protect the public?

Notwithstanding any discipline which might be otherwise be imposed in this matter, did complainant engage in an unreasonable delay in the investigation and prosecution of this matter causing prejudice to Dr. Marino to the extent that the Accusation should be dismissed on the grounds of laches?

FACTUAL FINDINGS

Dr. Marino's Background, Education and Training

1. James Marino, M.D. (Dr. Marino) was born in the Bronx, New York, on [redacted]. He graduated from high school in 1972. He attended Tufts University, where he majored in Chemistry and Biology, receiving a Bachelor of Arts degree in 1975. Dr. Marino attended Howard University Medical School, where he participated in an accelerated honors program, graduating with a Medical Doctorate in 1978.

Dr. Marino completed a one-year surgical internship at the University of California, San Diego, School of Medicine in 1979. He completed a four-year orthopedic residency at the same institution in 1983.

Dr. Marino was board certified by the American Board of Orthopaedic Surgery in 1985. He is a member of the Western Orthopaedic Academy, the North American Spine Society, and the International Intradiscal Therapy Society. He is a Qualified Medical Evaluator with the State of California.

Dr. Marino held staff privileges at several San Diego County hospitals including Donald Sharp Memorial Hospital, Scripps Memorial Hospital and Pomerado Hospital. Dr. Marino's hospital staff privileges have never been revoked, although they are now inactive.

2. Dr. Marino entered private medical practice in the field of general orthopedic surgery in 1983. He initially had a solo practice with offices in the Mira Mesa and La Jolla areas. In 1996, Dr. Marino became associated with Orthopedic Surgery Associates of North County, a group of orthopedic surgeons with offices in Poway.

After moving his practice to Poway, Dr. Marino began specializing in lumbar spinal surgery; by 1998, his practice was limited to that subspecialty. Dr. Marino was the only full-time spine surgeon practicing out of Pomerado Hospital from 1998 through 2002.

3. In the mid-1990s, Dr. Marino became intrigued with the idea of performing lumbar spine surgery with endoscopic technology.[1] He visited Philadelphia, Pennsylvania,

[1] An endoscope is a device with a light attached which is used to look inside the body. Endoscopes may be equipped with tiny surgical instruments. A medical procedure using any type of endoscope is called an endoscopy or

where he met with Parviz Kambin, M.D. (Dr. Kambin), whom Dr. Marino described as a pioneer in the field of endoscopic spinal surgery. Dr. Marino and approximately 40 other interested orthopedic surgeons spent a week with Dr. Kambin learning about endoscopic spinal surgery. A part of the curriculum involved spending one morning and one afternoon working on cadavers under supervision.

From 1994 through 1996, Dr. Marino performed endoscopic percutaneous[2] discectomies in the care of eight to ten patients. According to Dr. Marino, he stopped performing these surgeries because they were, at the time, "unsettled and unreliable."

In 1997, Dr. Marino learned more about endoscopic percutaneous discectomies by attending the International Intradiscal Therapy Society's annual meeting. Dr. Marino joined the society. After 1997, Dr. Marino continued attending meetings, conferences and seminars involving minimally invasive spinal surgery, presenting poster and oral presentations at several conferences.

Before founding NuVasive, a medical device development company, Dr. Marino participated in a cadaver dissection at UCSD to learn more about minimally invasive spinal surgery with endoscopic techniques. In 1998, he spent three full days dissecting cadavers at conferences in Tennessee, Dallas and Chicago. By June 2000, and before the surgery involving patient Ronald B., Dr. Marino employed percutaneous endoscopic surgical techniques in the treatment of several patients with spinal problems. None of these procedures involved a transiliac approach through the psoas muscle.

4. In 1998, Dr. Marino founded NuVasive, a business venture engaged in the design, development and marketing of products used in the surgical treatment of spine disorders. When he was with NuVasive, Dr. Marino conceptualized and helped develop several devices including a surgical frame, a nerve avoidance system, and specialized surgical instruments. According to Dr. Marino, he consulted with many "world class spine surgeons" who visited the NuVasive headquarters in La Jolla.

Dr. Marino's relationship with NuVasive ended in 2002.

5. In November 2003, Dr. Marino discontinued his spinal surgery practice for two reasons. First, he was unable to stand comfortably for prolonged periods of time due to a post-polio syndrome. Second, as a result of three medical malpractice settlements, the high cost of malpractice insurance coverage made his surgical practice financially unrewarding.

Dr. Marino currently engages in a non-surgical clinical orthopedic medical practice. He has offices in La Jolla and Poway.

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endoscopic. For example, laparoscopic surgery involves an endoscope inserted through a small incision in the abdomen or chest, and is used as an alternative to traditional gall bladder and chest surgery; arthroscopic surgery is endoscopic surgery performed on joints such as the knee or shoulder.

2 "Percutaneous" means passed, done or effected through the unbroken skin.

License History

6. On October 1, 1979, the Medical Board of California (the Medical Board) issued Physicians and Surgeon's Certificate No. G40978 to Dr. Marino.

There is no history of any discipline having been imposed against that certificate.

Jurisdictional Matters

7. On April 28, 2005, the Accusation was signed by complainant David T. Thornton, the Medical Board's Executive Director.

The Accusation alleged that in Dr. Marino' treatment of three patients – Ronald B., Susan K., and Kenneth D. – Dr. Marino engaged in gross negligence, committed repeated negligent acts, and demonstrated incompetence in connection with three low back surgeries from October 2000 through February 2001.

Dr. Marino, through counsel, denied the allegations and raised the affirmative defense of laches.

On April 4, 2006, the evidentiary record was opened. Jurisdictional documents were presented. Opening statements were given. On April 4-7 and 10-12, sworn testimony and documentary evidence was received. On April 12, closing arguments were given, the record was closed, and the matter was submitted.

Degenerative Disc Disease – Herniated Discs - Spinal Stenosis

8. *Degenerative disc disease.* The term "degenerative disc disease" describes normal changes in spinal discs associated with the aging process. Degenerative disc disease takes place throughout the spine; however, it most often involves the discs in the lower part of the cervical spine and the lumbar spine. A loss of fluid (known as desiccation) reduces the ability of the discs to act as shock absorbers, makes them less flexible and smaller, and narrows the distance between the vertebrae.

Disc herniation. A common cause of low back and radiating leg pain is a ruptured or herniated disc. With acute or repetitive trauma and/or desiccation, tiny tears or cracks form in the outer annulus or capsule of the disc. The nuclear material inside the disc may be forced out through the tears or cracks, causing the disc to bulge, extrude, rupture, or break into fragments. The presence of disc material outside its normal anatomical confines may compress the spinal cord and cause a variety of symptoms including dull or sharp pain, muscle spasm or cramping, radiating leg pain, leg weakness and/or loss of leg, ankle and foot functions. Sneezing, coughing, or bending may intensify the pain.

Spinal stenosis. Spinal stenosis involves the narrowing of the spinal canal - the open space in the spine surrounding the spinal cord. Spinal stenosis may be congenital or it may instead be the result of the degenerative process. With spinal stenosis, pressure can be placed on the spinal cord and on nerves where they exit vertebrae, leading to pain and possibly affecting nerve function. The symptoms of lumbar spinal stenosis are fairly consistent: standing and walking become intolerable, even though sitting or driving a car may not cause any discomfort.

A variety of diagnostic techniques are used to diagnose degenerative disc disease, a herniated disc, and/or spinal stenosis, including x-rays, myleograms, discograms, CT scans, and MRI scans.

Conservative Treatment

9. Medical practitioners often use the term "conservative treatment" to describe any kind of therapeutic treatment for back problems that does not involve surgery including rest, medication, exercise, and physical therapy. If initial conservative measures fail, epidural steroid injections (nerve blocks) are sometimes administered.

Surgical Treatment

10. When all else fails, spinal surgery may be the only viable treatment option for a patient suffering from debilitating back pain caused by degenerative disc disease, a herniated disc, or spinal stenosis. There are a variety of surgeries and techniques to address all of these problems, some of which are described below.

Open Surgery: The classic surgical technique to treat a herniated disc is to perform a laminotomy and discectomy. This technique is performed by making an incision down the center of the back in the area above the herniated disc. Once the incision is made through the skin, the muscles are moved to the side, which enables the surgeon to visualize the back of the vertebrae. X-rays may be required during this part of the surgery to make sure that the correct vertebra has been exposed. A small opening is made between the vertebrae where the disc has extruded, ruptured, or fragmented, which allows the surgeon to see into the spinal canal. Once this is accomplished, the surgeon moves the nerve roots out of the way to see the intervertebral disc. The surgeon locates any disc material that has migrated into the spinal canal and removes it, with the goal of eliminating any pressure and irritation on the nerves of the spine. Using small instruments that fit inside the disc, the surgeon then removes as much of the remaining nuclear material inside the disc as possible to prevent it from extruding. After the procedure is completed, the muscles of the back are returned to their normal position around the spine. The skin incision is repaired with sutures or metal staples.

Foraminotomy: A foraminotomy is a surgical procedure performed to enlarge a foramina, the passageway where [through which?] a spinal nerve exits the spinal canal. During a foraminotomy, the spine surgeon removes any bone or tissue that obstructs the

passageway and compresses the spinal nerve root, eliminating the source of the inflammation and pain.

Fusion: The most common reason for performing a spinal fusion is to alleviate low back pain related to painful motion of the vertebrae. The goal is to eliminate motion at a painful segment, thereby reducing the pain caused by the motion. The abnormal and painful motion may be caused by painful discs (discogenic pain or degenerative disc disease), abnormal slippage of the vertebra (spondylolisthesis or spondylolysis), and/or other degenerative spinal conditions including but not limited to facet joint degeneration.

A spinal fusion may involve using a bone graft to cause two vertebral bodies to grow together into one long bone. Bone can be taken from the patient during the spinal fusion surgery (autograft bone), or it may be harvested from other sources (allograft bone). Fusion may also involve the use of specially designed surgical hardware including rods and screws.

Microdiscectomy: Within the past 20 years or so, vast improvements were made in the equipment available to spinal surgeons performing traditional laminotomies, discectomies, foraminotomies and/or spinal fusions. The microdiscectomy procedure is essentially the same as the classic, open surgical procedure described above, but it requires a much smaller incision. The advantage of microdiscectomy over the traditional approach is that a smaller incision results in less damage to the healthy parts of the spine during the operation, as well as a faster recovery period in most instances.

To see through the smaller incision, the surgeon uses an operating microscope or loupes. A small incision is made in the back just above the area where there is an anatomical problem capable of surgical correction. The muscles are moved aside and the vertebrae are visualized, the operation is performed in the same manner as in the open surgical approach described above. Intraoperative x-rays are often used to verify that the surgeon is operating on the disc that is causing the patient's symptoms.

Endoscopic Discectomy: Many surgical procedures were revolutionized by the development of surgical devices utilizing fiber optic light and miniature TV cameras (i.e., endoscopic devices). For example, torn cartilage in the knee is now routinely removed with the arthroscope, and gallbladders are routinely removed with the laparoscope. A similar approach may be evolving in the field of spinal surgery.

The notion is that if microdiscectomy does less damage because of a smaller incision, endoscopic discectomy might do even less damage than miscrodiscectomy because of an even smaller entry wound with a percutaneous incision. While endoscopic spinal surgical procedures appear to be evolving, they are not yet commonplace.

The endoscopic procedure proceeds on the same premise as the surgeries outlined above, but even smaller incisions (known as stab incisions) are made to access the body. A special magnified TV camera and very small surgical instruments are placed into the body through the incision and are ultimately directed into the spinal canal through the cannulas (a

slender tube inserted into a body cavity or duct). The surgeon indirectly visualizes the operative field in carrying out the surgical procedures. Rather than looking directly at the spine as in the classic open surgery or in a microdiscectomy, the surgeon performing percutaneous endoscopic spinal surgery watches a TV screen. As the surgeon watches the screen, he or she directs specially designed instruments to remove disc material and to perform other surgical functions including fusions. The endoscopic procedure theoretically involves less surgical trauma. Its drawback is that the surgeon does not directly see what he is doing. One of the promising features of the endoscopic techniques is the minimization of scarring around the nerves, a common cause of failure in open surgical procedures.

Surgical Complications: Well known surgical complications exist in any spinal surgery include anesthesia complications, blood clots, infections, and spinal cord injuries.

Patient Ronald B. - The Novel Transiliac Procedure

11. Ronald B. was born on [redacted] He became a Senior Vice President with Arrowhead General Insurance and moved to San Diego.

12. Between February 3, 2000 and June 14, 2000, Ronald B. treated with Edward Venn-Watson, M.D. (Dr. Venn-Watson) for worsening bilateral, radiating low back pain. An MRI scan demonstrated a severe central spinal stenosis at L4-5, with a moderately severe encroachment narrowing both foramina and a bulging annulus on the right at L4-5. A course of conservative treatment, including a series of epidural steroid injections and physical therapy, failed. Dr. Venn-Watson referred Ronald B. to Dr. Marino.

13. Ronald B. first met with Dr. Marino on June 23, 2000. Ronald B. had been taking two to four Vicodin tablets daily for four or five months for pain. After a couple of visits, Ronald B. underwent a diagnostic procedure known as a lumbar discography. The results were consistent with severe concordant pain at L3-4 and L4-5 with evidence of disruption and annular tears. By then, Ronald B. was in severe pain. He was taking up to four Vicodin at a time and was barely able to stand.

14. On October 13, 2000, Dr. Marino discussed treatment alternatives with Ronald B., including conservative management (which had not been helpful) and surgery. With regard to surgery, Dr. Marino advised Ronald B. of the traditional surgical approaches and "a minimally invasive percutaneous approach." Dr. Marino told Ronald B. he had performed the proposed minimally invasive percutaneous approach on cadavers and baboons, but not on any living human patient. Dr. Marino told Ronald B. the minimally invasive surgery might last four to six hours.

It was not entirely clear if Dr. Marino said he would use an endoscopic surgical approach across the ilium and through the psoas muscle, a very novel medical procedure. Whatever Dr. Marino said, informed consent was not identified as an issue in the Accusation and it is of little importance here, except insofar as it was raised as a factual defense.

15. On October 13, 2000, Ronald B. signed a document entitled Research Subject Information and Consent Form. Ronald B. specifically consented to a procedure involving "intraoperative nerve surveillance in minimally invasive spinal decompression and fusion." Dr. Marino was described as the "investigator" and the study was sponsored by NuVasive, the company developing the nerve surveillance equipment.

The consent form stated the purpose of the research study was twofold: "first to determine whether adding several additional nerve-function tests to your surgical procedure can improve the outcome of your surgery; and second, to evaluate the effectiveness of an experimental (investigational) device in helping your surgeon perform these tests."

The consent form stated, "Because the study may require the surgeon to lengthen your surgery by approximately 5 to 15 minutes to permit placement of the extra electrode, your operative procure, and the length of your anesthesia, will be lengthened by this amount." The consent form also stated, "Other than the two types of nerve monitoring, your surgery will proceed exactly as it would if any were not participating in this research study." The consent form did *not* describe the surgical approach as being experimental or novel.

16. On October 20, 2000, at 6:15 a.m., Ronald B. signed another consent form related to a "lumbar fusion L3 L4 L5 with iliac bone graft" which was presented to him at the HealthSouth UTC Surgicenter immediately before surgery. Paragraph 3 of the HealthSouth consent form specifically mentioned possible complications including "nerve injury."

The consent forms did not purport to waive any act of negligence. The fact that Dr. Marino was engaged in a novel surgery involving an investigational protocol did not permit him to act in a manner inconsistent with existing standards of care.

17. After signing the final consent, Ronald B. was taken to the operating room. Brian Smith, M.D. (Dr. Smith) was the attending anesthesiologist.

The surgical plan was to remove disc material at L3-4 and L4-5 and to fuse the L3-4 and L4-5 vertebrae using endoscopic techniques. During surgery Ronald B. would be situated in the prone position on a padded Kambin surgical frame and his lumbar spine would be approached across the iliac crest through the psoas muscle with the use of a sterotactic guide (which Dr. Marino helped develop). Visualization would be accomplished using an image intensifier. A NuVasive INS-1 intraoperative nerve monitoring device (the subject of the WIRB investigational protocol) and a Viking Nicolete intraoperative nerve monitoring device (a predecessor device) were going to be used during the procedure to inform Dr. Marino if he was approaching vital nerves during surgery and to establish the fact of decompression of the nerve roots. Various NuVasive instruments, including specially designed cannulas, would be used during the procedure. Dr. Marino and other participants were required to wear a heavy lead shield during the procedure because of the radiation accompanying fluoroscopy.[3]

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[3] Fluoroscopy uses a continuous beam of X-rays to evaluate structures and movement within the body.

General anesthesia was administered at 7:10 a.m. The operative procedure began at 8:35 a.m. and it continued until 8:00 p.m. It took about six hours to perform the surgery at L3-4 and about another six hours to perform the surgery at L4-5. During those surgeries, Ronald B. remained immobile in the prone position. Between the surgeries, Ronald B. was placed in reverse Trendelenburg position[4] for 20 minutes to optimize the flow of blood to the head. Anesthesia was discontinued at 8:27 p.m. There were numerous engineers and others from NuVasive present throughout the surgery.

According to Dr. Marino's testimony the surgery was very lengthy, but it went "spectacularly well." It took a long time for Dr. Marino to access the disc space with the transiliac approach and the removal of the disc material was incredibly slow because such small equipment was being used. Dr. Marino was not aware of any nerve injury occurring during the procedure. Dr. Marino's operative report, which was dictated immediately after the procedure, stated:

> "The patient tolerated the procedure well, was discharged to the recovery room with no more than approximately 500 cc blood loss . . ."

18. However, when Ronald B. tried stand up the next day, he unexpectedly experienced profound bilateral weakness in his lower extremities and could not do so. Ronald B. also suffered severe back discomfort.

19. Dr. Marino immediately had Ronald B. transferred from HealthSouth to Scripps Memorial Hospital, where Ronald B. was admitted on October 21, 2000 for a diagnostic evaluation and therapeutic treatment. Dr. Marino's admitting diagnosis was "Femoral nerve neuropraxia[5] secondary to surgical intervention."

On October 24, 2000, Ronald B. was discharged from the hospital and was transferred to a rehabilitation facility. Dr. Marino's discharge diagnosis was "Postoperative neuropraxia bilaterally femoral and obturator nerves." In the discharge summary, Dr. Marino wrote:

> "The patient is a 55-year-old-gentleman [who] sustained a neurologic deficit following an extended lumbar fusion procedure resulting in bilateral obturator and femoral nerve injuries . . ."

20. By letter dated February 20, 2001, Ronald B. formally discharged Dr. Marino as his treating physician, stating Dr. Timothy A. Peppers (Dr. Peppers) and Dr. Raymond J.

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[4] Trendelenburg's position is a position in which the patient is on an elevated and inclined plane, with the head down and legs and feet over the edge of the table. It is used in operations to push abdominal organs towards the chest. The reverse Trendelenberg position is self-explanatory.

[5] Neuropraxia is the physiological interruption of an anatomically intact nerve. In this condition there is minimal damage. The axons are intact but conduction is lost. It involves a transient lesion and recovery is spontaneous after a few days or weeks.

Linovitz (Dr. Linovitz), each of whom was an orthopaedic surgeon specializing in spinal surgery, would assume the responsibility.

21. On April 16, 2001, Dr. Peppers, who was assisted by Dr. Linovitz, performed an anterior lumbar interbody fusion at L3-4 and L4-5 (removing the previous interbody grafts), placed posterior spinal instrumentation from L3 through L5, performed a L4 laminectomy and a right-sided L3 hemilaminectomy for a "pseudoarthrosis, status post previous attempted L3-4 and L4-5 interbody fusion percutaneously" and a "post-laminectomy syndrome, lumbar spine, with right lower extremity neurologic deficit." The operative report stated preoperative imaging studies showed "evidence of pseudoarthrosis with nonhealing of the interbody grafts at L3-4 and L4-5." During the surgical procedure, motion was identified as the interbody grafts were removed.

Ronald B. was discharged from the rehabilitation facility on April 23, 2001, with a recommendation that he be followed by Robert Wailes, M.D. (Dr. Wailes), a pain specialist.

22. On January 28, 2002, Dr. Wailes inserted a spinal cord stimulator in Ronald B.'s spine to relieve pain arising from a "failed back syndrome."

23. In retrospect, it was concluded by virtually all the experts that Ronald B.'s neurologic injuries were likely secondary to stretching from his prolonged prone positioning during surgery and/or a neuropathy secondary to the insertion of cannulas through the psoas musculature. Ronald B. is presently on a daily regimen of 160 mg of OxyContin, 80 mg of Percocet, and 900 mg of Neurotonin. He has retired and lives in Texas.

Patient Susan K. – Wrong Level Surgery

24. Susan K. was born on [redacted]. After graduating from the University of California, San Diego, she married, had a daughter, and became employed as a software engineer.

Susan K. experienced low back problems in late 2000, which included radiating pain down her right leg. She was seen by several physicians. She was provided with conservative treatment including anti-inflammatory medications, epidural injections, and physical therapy. She came under the care of James M. Bried, M.D. (Dr. Bried). An MRI scan revealed the presence of a herniated and extruded disc pressing on the nerve root at L5/S1. When further conservative treatment failed to alleviate her symptoms, Dr. Bried referred Susan K. to Dr. Marino, his colleague.

25. Dr. Marino first met with Susan K. on January 9, 2001. He obtained a history of the present illness, a past medical history, performed a physical examination, reviewed the MRI scan (which he believed was consistent with a contained broad based disc protrusion at L5-S1, traversing the S1 nerve root), and spoke with Susan K. concerning her options. With regard to those treatment options, Dr. Marino's chart note stated:

"We have presented the options of nonoperative as well as operative management, including a variety of operative treatments, such as hemilaminotomy, discectomy versus percutaneous lumbar discectomy. She has been apprised of the attendant risks and benefits, including the outcomes associated with each procedure and the uncertainties associated with the percutaneous procedure and its lack of long-term follow-up studies in its current form.

Understanding these attendant risks and benefits, including infection recurrent disc herniation, nerve injury production persistent motor or sensory deficits, the patient has consented to percutaneous lumbar discectomy which will be arranged in the near future."

26. Susan K. recalled telling Dr. Marino that open back surgery "was not an option" because she considered it to be too invasive and too dangerous. She did not understand that it might be necessary to convert the percutaneous procedure to an open procedure, even though Dr. Marino was certain he explained that to her. She believed that while a nerve injury was possible, it was a very low risk.

27. Susan K. was admitted to Pomerado Hospital on January 10, 2001. She signed a consent to surgery which identified the following surgical procedure: "Percutaneous lumbar discectomy L5 S1, spinal monitoring."

The consent form also contained provisions indicating "All operations and procedures may involve risks of unsuccessful results, complications, injury, or even death, from both known and unforeseen causes . . ." The consent authorized Dr. Marino to perform the identified procedure and "any different or further procedures which, in the opinion of your supervising or attending physician or surgeon, may be indicated due to any emergency . . ."

Whatever Dr. Marino told Susan K., informed consent was not identified as an issue in the Accusation and it is of little importance here, except insofar as it was raised as a factual defense.

28. After signing the consent, Susan K. was taken to the operating room. Marc Zinser, M.D. (Dr. Zinser) was the attending anesthesiologist.

The surgical plan was to perform a discectomy and foraminotomy at L5/S1 using endoscopic techniques. During surgery Susan K. would be situated in the prone position on a Kambin frame and her lumbar spine would be approached across the iliac crest through the psoas muscle with the use of a sterotactic guide. Visualization would be accomplished with an image intensifier. A NuVasive INS-1 intraoperative nerve monitoring device would used during the procedure. NuVasive instruments, including cannulas, would be used during the percutaneous procedure. The procedure was very similar to the surgical approach involving Ronald B. less than six months before.

Anesthesia was administered at 8:55 a.m. The operative procedure began around 10:00 a.m. An effort was made to access to the L5/S1 interspace without having to remove any iliac bone, but that effort was thwarted by the presence of the iliac crest at its very upper margin. Efforts were then made to bore through the iliac crest, but that proved almost impossible. According to Dr. Marino's operative report, he decided after several attempts to try to get the percutaneous instruments around the iliac crest, "this was not productive and [I] elected to proceed to an open hemilaminotomy disckectomy procedure."

According to the anesthesiologist's notes, a "decision to go to open case" was made at 11:55 a.m. Susan K. was prepared for the open surgery. There was not a medical emergency because without proceeding to an open procedure, there was no risk of life, limb or function.

According to the operative report, a midline incision was made at L5/S1, "confirmed our location with a standard lateral x-ray." Portions of the inferior lamina on the right side at L5 and the ligamentum flavum were removed and the spinal canal was opened. Bleeding was controlled. According to the report, the "traversing S1 nerve root was identified, retracted toward the midline and a small linear incision created in the annulus after which . . . rongeurs were used to remove disc material. A complete foraminotomy in the entrance zone of the foramen was created by using a power bur and Kerrison rongeur . . . . Intraoperative neuromonitoring showed considerable lowering of depolarization current threshold on the right side associated with both the L5 and S1 myotomes . . . [and after closing]. . . . The patient was discharged to the recovery room . . . without any overt complications."[6]

Surgery concluded at 2:12 p.m. Anesthesia was discontinued at 2:27 p.m.

29. When Dr. Marino met with Susan K. in the recovery room, he observed profound weakness and nerve loss in her right foot. He ordered a myelogram and CT scan.

30. The radiologist, Richard Price, M.D. (Dr. Price), spoke with Dr. Marino and said the images showed postoperative changes at L4-5, on the right, and a disc protrusion with a free fragment at L5/S1. Dr. Marino immediately reviewed the diagnostic images and concluded he had performed surgery at the wrong level.

31. Dr. Marino told Susan K. and her husband about the wrong level surgery. He told them the nerve monitoring equipment he had used (the NuVasive INS-1) gave him no indication of any nerve dysfunction at any time during surgery. He asked for permission to perform an open surgery to remove the herniation and fragment at L5/S1, believing the use of the fresh surgical track would minimize surgical trauma from a second surgery.

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[6] Dr. Marino later added a handwritten note to the operative report which stated:

"Post operative CT scan demonstrated inferior hemilaminotomy to have occurred at the right L-4 not right L-5 as was thought and intended."

32. At 6:00 a.m. on January 11, 2001, Susan K. signed another consent, this time agreeing to a "fusion of L5-S1 with exploration & decompression of right L5 nerve root and iliac bone grafting." Thereafter, Susan K. withdrew her consent. She spoke with Marc Stern, M.D. (Dr. Stern), a neurosurgeon, to whom she was referred by Dr. Marino, and obtained a second opinion.

33. Susan K. decided not to have additional surgery following her consultation with Dr. Stern. She was discharged from the hospital and remains under Dr. Stern's care. Her condition continues to improve slowly.

34. The defect at the L5/S1 level has never been surgically addressed. Susan K. has daily back pain with some radiation, for which she takes Vicodin and Motrin.

Patient Kenneth D. – The Dural Tear

35. Kenneth D. was born on [redacted]. After graduating from college, he was on active duty with the United States Marine Corps. Following his active duty, Kenneth D. became an executive officer with several high tech companies.

36. Kenneth D. experienced low back problems in 1999, including radiating pain down his left leg. Kenneth D. came under Dr. Bried's care.

X-rays revealed diffuse mild degenerative disc disease at L4-5 and L5-S1. An MRI scan revealed mild to moderate spinal stenosis. Kenneth D. obtained conservative treatment including rest, exercise, physical therapy, anti-inflammatory medications, and a series of epidural injections, but he remained quite symptomatic. On January 15, 2001, Dr. Bried referred Kenneth D. to Dr. Marino.

37. Kenneth D. first met with Dr. Marino on January 19, 2001. Dr. Marino took a history, performed a physical examination, reviewed x-rays and the MRI scan, and discussed treatment alternatives. According to Dr. Marino's chart note:

> "It's the patient's desire to proceed with hemilaminotomies to the left of midline at the L3-4 and L4-5 level. He's aware of the attendant risk and benefits including the potential for nerve injury, cerebral spinal fluid leakage, and persistent and/or recurrent pain."

38. Open spinal surgery was scheduled for February 19, 2001, at Pomerado Hospital. The proposed surgical procedures included bilateral hemilaminotomies and foraminotomies at the L3-4 and L4-5 levels.

39. On February 19, 2001, following his admission to Pomerado Hospital, Kenneth D. was taken to the operating room where he was anesthetized and intubated. He was placed in a kneeling position on an Andrews frame. A midline incision was made and the muscles and soft tissues over the operative site were retracted. The subcutaneous vessels

were cauterized. A Kocher clamp was placed on the posterior portion of the vertebra at the L4 level to identify the dissection level. Dr. Marino removed disc material at that level, compressing the spinal cord and nerve roots.

During this portion of the procedure, Dr. Marino had been offered a rongeur (an instrument used to remove bone) that was too large for the task. When Dr. Marino asked for a rongeur more appropriate to the task, he was told one was not available. Dr. Marino then asked that one be obtained from a nearby hospital; in the interim, Dr. Marino decided to proceed with the surgery by using a smaller ronguer, which required him to use a power drill with a bur to thin the vertebrae. When Dr. Marino asked for an Anspach drill and bur, he was told it was unavailable, but he was told a Stryker TPS drill with bur was available. Dr. Marino had used that model drill and bur about half a dozen times before and he was somewhat familiar with it. He used the Stryker drill and bur for 10 to 20 minutes to thin the lamina at L4 without incident. According to his operative report:

> "Eventually ligamentum flavum was removed extending out into the foramen at the L4-5 level and with additional bone removed from the upper portion of the fifth lumbar vertebra."

Dr. Marino then turned his attention to the L3-4 level, where the power bur was used to remove bone. According to his operative report:

> "Unfortunately, even under careful visualization with use of a Fraser suction I encountered the dura, tearing it slightly, and causing small cerebrospinal fluid leakage. This was ultimately repaired with 6-0 Durelon to a watertight seal . . . I elected to use fibrin clot to reinforce the repair of the dura . . . by administering equal parts of cryoprecipiate and 10 percent calcium chloride solution with thrombin . . . A hemilaminotomy and foraminotomy was created to the right of the midline at the L4-5 level and also at the L3-4 level without incident. We had Valsalva maneuver performed on several occasions without evidence of any cerebrospinal fluid leakage. The wounds were closed after thorough irrigation with antibiotics over a drain the patient was discharged to the recovery room in good condition without apparent adverse consequence other than a single dural [tear] which was repaired."

The operative report did *not* mention the Stryker TPS drill and bur as being a contributory factor in causing the dural tear.

40. Dr. Marino testified that immediately before the dural tear, he was holding the Stryker device in his major/right hand, the Fraser suction device in his left hand. He was lightly "painting" the lamina of the L-3 vertebrae from the left side of the patient's body, removing bony material to access the disc. He thought he was in an area of safety. The bur was rotating at 50,000-60,000 rpm when it "moved violently" 1 to 2 cm to the right and contacted the ligamentum flavum, which wound around the bur and pulled the bur into the spinal canal. Before that occurred, Dr. Marino said he suspected the ligamentum flavum was sufficiently robust to prevent the bur from penetrating into the dura. When the bur engaged

the ligamentum flavum, Dr. Marino immediately released the hand switch on the Stryker device, but he observed central spinal fluid leaking from a small tear in the dura, which he immediately attempted to repair.

41. That evening, Dr. Marino told Kenneth D. what had occurred. At the time, Kenneth D. had numbness in the left foot and weakness of the left ankle and foot. The next day, Kenneth D. had numbness in the scrotum and rectum with a weak anal sphincter tone. A CT myelogram revealed narrowing of the field and the cauda equina, particularly at the L3-4 level.

Dr. Marino thought there might be an external compression and performed a wound exploration on February 20, 2001. There was no evidence of a hematoma or compression phenomena on investigation.

42. On February 23, 2001, Dr. Marino dictated a discharge summary. In that report, he stated:

> "On the day of admission the patient underwent bilateral hemilaminotomy and foraminotomy procedures at the L3-4 and L4-5 levels. During the course of the procedure, an inadvertent dural laceration occurred with the power bur and the patent had a dural repair. Unfortunately, the patient woke up with significant deficits involving primarily his sacral nerve roots and also the left L-5, S1 motor and sensory areas. The deficits in the sacral region were not noted really until the first postoperative day. The patient had reported some scrotal numbness the evening of the procedure which I had originally attributed perhaps intraoperative positioning in this very obese gentleman, but later on examining the following day noted him to have loss of rectal tone and significant dense anesthesia in the perianal region."

The discharge summary stated Dr. James Nelson, a neurologist, concurred with Dr. Marino's diagnosis of bilateral lower and upper sacral nerve dysfunction, probably secondary to a cauda equina trauma resulting from the power bur intrusion into the intrathecal space.

Kenneth D. was transferred to a rehabilitation facility. Dr. Marino said he advised someone at Pomerado Hospital the drill might be defective.

43. Dr. Marino spoke with John Lauria (Lauria), a Stryker representative, at a medical conference in San Francisco and related his experience with the Stryker drill and bur. Dr. Marino said he was told there were "similar reports." Whether this was true is unknown. Lauria reportedly recommended Dr. Marino reverse the rotational direction of the drill when operating on the patient's left side. However, this reported recommendation did not make sense since the bur was designed to work when rotating in only one direction.

44. On April 9, 2001, Dr. Marino wrote a letter to Stryker. He described the incident involving Kenneth D. and the Stryker device, theorizing the "surgical mishap" was the result of a "potentially hazardous performance characteristic of the TPS instrument." He

stated he had used the device properly and for its intended purpose. A copy of Dr. Marino's letter was directed to Lauria and another copy was directed to Pomerado Hospital's Surgical Department's supervisor. He received no response.

45. Dr. Marino followed Kenneth D. In a chart note dated May 11, Dr. Marino stated:

> "He and I discussed the possible contributory effects of various conditions during his surgical procedure. I related to him my concerns regarding my inability to restrain the caliber at the time it veered from the position in which I had it and its penetration into the ligamentum flavum."

46. Kenneth D. has no feeling in his left leg, but he taught himself how to balance himself on his feet. He starts bowel movements with his finger. He is incontinent of bladder and he wears diapers, which he changes three times a day. Kenneth D. remains employed in the computer industry.

Relevant Standards of Care

47. The "standard of care" requires a spinal surgeon to exercise that degree of skill, knowledge and care ordinarily possessed and exercised by other reasonably careful spinal surgeons in similar circumstances. The standard of care is a matter peculiarly within the knowledge of experts; it presents a basic issue which can only be established by expert testimony.[7]

Before discussing relevant standards of care, several matters should be noted.

First, the application of the legal doctrine of *res ipsa loquitur* ("the thing speaks for itself") does not apply. The medical procedures involved were not matters of common knowledge, and expert testimony was required to establish that Dr. Marino violated a standard of care, unless the common knowledge of laymen supported a finding of negligence (e.g., where the surgeon amputated the wrong leg, or where there was injury to a part of the body not within the operative field). "There is an element of drama and of the freakish and improbable in the typical *res ipsa loquitur* case."[8] A violation of a standard of care is not established because surgery was unsuccessful or because the surgeon made an error in judgment which was reasonable under the circumstances.[9]

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[7] *Williams v. Prida* (1999) 75 Cal.App.4th 1417, 1424; *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 1001/

[8] *Curtis v. Santa Clara Valley Medical Center* (2003) 110 Cal.App.4th 796, 801.

[9] *Fraijo v. Hartland Hospital* (1979) 99 Cal.App.3d 331, 343.

Second, inferring negligence because an injury rarely occurs in a particular kind of surgery places an unfair burden on the medical profession and discourages the use of new procedures which may pose inherent risks even in the exercise of due care.[10]

Third, the standard of care does not fault a surgeon for choosing among different methods that have been approved by the profession, even if the choice later turns out to have been a wrong selection or one not favored by other members of the profession.[11]

Fourth, when a procedure inherently involves a known risk of death or serious bodily harm, the physician must disclose the possibility of such an outcome and explain it to the patient in lay terms.[12] However, obtaining a patient's informed consent to does not relieve a surgeon from exercising due care during the surgery.[13]

48. *Complainant's Expert Witnesses*

A. Raymond J. Linovitz (Dr. Linovitz): Dr. Linovitz is a highly trained, highly experienced orthopaedic surgeon specializing in spinal surgery. Dr. Linovitz did not provide expert testimony concerning relevant standards of care, but his percipient testimony as an experienced spinal surgeon established that a percutaneous endoscopic discectomy via a transiliac approach through the psoas musculature without direct visualization was so rare that he was unaware of such a procedure.

B. Richard J. Barry, M.D. (Dr. Barry): Dr. Barry received an undergraduate degree in Physical Sciences from San Jose State University in 1971. After graduating from college, Dr. Barry was on active duty as a commissioned officer with the United States Air Force. After completing pilot training, he served as a pilot in Vietnam and taught flying in Mississippi. Following his discharge from active military duty in the mid-1970s, Dr. Barry was admitted to the University of Mississippi, School of Medicine, where he received a Medical Degree with honors in 1980. Dr. Barry completed an orthopaedic residency at the University of Washington in Seattle in 1985.

Dr. Barry returned to active duty with the United States Air Force from 1985-1989, and became Chief of the Orthopaedic Clinic at Travis Air Force Base. He served as a senior aviation medical examiner for the FAA from 1981-1989.

Dr. Barry entered private practice in Davis, California, in 1989, with an orthopaedic medical group now known as Valley Oak Orthopaedics, where he remains. He serves as an unpaid Assistant Clinical Professor of Medicine with the University of California, Davis,

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10 *Curtis v. Santa Clara Valley Medical Center* (2003) 110 Cal.App.4th 796, 803.

11 *N.N.V. v. American Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1384.

12 *Mathis v. Morrissey* (1992)11 Cal.App.4th 332, 340.

13 See *Belshaw v. Feinstein* (1968) 258 Cal.App.2d 711, 726.

School of Medicine, Department of Orthopaedic Surgery. Dr. Barry specializes in the treatment of spinal conditions, with a particular interest in spine microsurgery.

Dr. Barry was board certified by the American Board of Orthopaedic Surgery in 1986 and has since been recertified. In 1999, he was certified by the American Board of Spine Surgery, a relatively new organization which was approved as a specialty certification board by the Medical Board in May 2002.

Dr. Barry is a fellow of the American College of Surgeons, the North American Spine Society, and the American Academy of Orthopaedic Surgeons. He is a member of the Board of Directors of the California Orthopaedic Association. Dr. Barry is on staff at local hospitals and surgery centers in the Sacramento area.

49. *Respondent's Expert Witnesses*:

A. Dr. Marino: Dr. Marino testified as both a percipient and expert witness. Dr. Marino's qualifications as an expert are set forth in factual findings 1-4.

B. Ernest B. Marsolais, M.D., Ph.D. (Dr. Marsolais): Dr. Marsolais received a Bachelor of Arts degree in General Science from the University of Iowa, Iowa City, Iowa, in 1960. He was admitted to the Medical University of Iowa and obtained a Medical Doctorate in 1953. He completed a general/plastic surgery internship at Columbia University, St. Luke's Hospital, in 1964.

Dr. Marsolais obtained a Master of Science degree in Engineering Mechanics from the Graduate University of Iowa, Dept of Mechanics and Hydraulics, in 1967, and a Ph.D. in Engineering Mechanics from that institution in 1969.

Dr. Marsolais completed an orthopedic surgery residency at the University of Iowa in 1970. He participated in an orthopaedic fellowship at the Wellesley Hospital in Toronto, Canada, in 1977-1978.

Dr. Marsolais holds memberships in the American Medical Association, the Iowa State Medical Society, the Iowa State Orthopaedic Society, the American Spinal Injury Association, the North American Spine Society, the Orthopaedic Rehabilitation Association, and the Orthopaedic Research Society.

Dr. Marsolais was on the faculty and taught orthopaedic surgery at Case Western Reserve University Medical School from 1970 until fairly recently. In 1990, he served as an adjunct associate professor of Biomedical Engineering, Case Western Reserve University.

Dr. Marsolais has authored numerous scholarly articles, including "Transforaminal and Posterior Decompressions of the Lumbar Spine: A Comparative Study of Stability and Intervertebral Foramen Area." That article was coauthored with several others and involved

a study to determine the feasibility of an endoscopic transforaminal approach as an alternative to conventional approaches. The article appeared in *Spine* in August 1997.

50. *Ultimate Factual Conclusions*:

The following factual conclusions were fairly framed by the allegations set forth in the Accusation and were supported by the clear and convincing evidence after weighing all the conflicting expert testimony.

A. *Ronald B.*: Dr. Marino engaged in a simple departure from the standard of care in connection with Ronald B.'s low back surgery.

Dr. Marino allowed Ronald B. to remain in a prone operative position for 12 hours, a situation an ordinary, reasonable and prudent orthopaedic surgeon would have avoided under similar circumstances. The highly novel surgical approach Dr. Marino planned on using was theoretically sound, but it was practically unproven. Dr. Marino became aware very early in Ronald B.'s surgery that he could not proceed as quickly as he had hoped. As a surgeon, he should have been aware that Ronald B. would not benefit from a prolonged surgery and there were unjustified risks associated with an unnecessarily prolonged surgery. Dr. Marino's concerns in testing the INS-1 device and in completing a novel surgical procedure clouded his sound medical judgment and unreasonably interfered with what was in Ronald B.'s best surgical interest - the least traumatic, most prompt decompression and fusion of L3-4 and L4-5. Dr. Marino should have converted the unduly prolonged percutaneous, endoscopic procedure to an open procedure, as he did with patient Susan K.

Neurologic injuries can occur from stretching, bruising, or severing nerves. The standard of care requires a spine surgeon to take reasonable steps to ensure a patient does not sustain injury during a surgery. With regard to patient positioning, a spinal surgeon should be concerned whenever a surgical procedure lasts more than three hours and the patient remains prone and immobile. Dr. Barry's testimony established Ronald B.'s operative positioning for twelve hours - a result of Dr. Marino's use of the NuVasive investigational instrumentation and a "very aggressive posteriolateral approach" across the ilium and through the psoas musculature to reach the L3-4 and L4-L5 disc spaces - constituted a simple departure from the standard of care. A minidiscectomy could have been performed in less than half the time with a probability of a better result because the surgeon would not have to disrupt the psoas muscle and could have actually seen what he was doing. Dr. Marino obviously knew of the obligation to convert to an open procedure when it was in his patient's best interest, as he demonstrated in the Susan K. procedure.

Dr. Marsolais' testimony that there was nothing inherently wrong with Ronald B. being in the prone position for 12 hours - because Dr. Marsolais had participated in and knew of surgical procedures lasting that long or longer in which there was no patient harm, surgeries which had to last that long - did not establish a standard of reasonable care under the circumstances.

However, Ronald B.'s surgery did not involve an extreme departure from the standard of care simply because it was novel (as Dr. Barry conceded) or because the INS-1 device was used (since it was used in conjunction with another proven and reliable nerve monitoring device). Dr. Marino provided Ronald B. with far more than scant medical care.

B. *Susan K.*: Dr. Marino engaged in a simple departure from the standard of care by performing a surgery at the wrong level and by inadvertently removing a healthy disc.

Wrong level disc surgery is not uncommon, but that does not mean that such surgery is reasonable or meets the standard of care. While Dr. Barry was not critical of Dr. Marino converting to an open surgical approach when he was unable to access patient Susan K.'s L-5/S-1 disc space through a percutaneous endoscopic approach, he was critical of Dr. Marino mistakenly operating at the L4-5 level when he observed a disc whose appearance was very inconsistent with the pathology that was shown in the pre-surgery imaging studies.[14] At that point, a reasonable and prudent spinal surgeon would not have simply assumed he was operating at the correct level and removed the disc; instead, the reasonable and prudent surgeon would have taken some further action to confirm he was at the correct level, such as requesting another intraoperative x-ray.

Gross negligence was not established.

Dr. Marsolais' testimony that he and all of his colleagues had engaged in wrong level disc surgery did not establish a standard of care, nor did his testimony about Dr. Marino's prudent conduct before the healthy disc was removed exonerate Dr. Marino from operating at the wrong level.

C. *Kenneth D.*: How careful should a spine surgeon be when he uses a drill with a bur that rotates at 50,000-60,000 rpm in close proximity to the spinal cord? According to Dr. Barry and Dr. Marsolais, the answer is very, very careful, because the risk of harm and the injuries resulting from a surgical misadventure can be so devastating.

Dr. Barry believed the standard of care required a spine surgeon using a high-speed power instrument, such as a drill and bur, to anticipate irregular movements of the device (i.e., "jumping" or "chattering") during surgery and to take precautions to avoid any injury if that should happen. Things do not always go smoothly and as planned during surgery. The surgeon should avoid penetrating structures such as the ligamentum flavum or disrupting nerve roots in the cauda equina. Dr. Barry believed Dr. Marino's failure to take adequate and reasonable precautions to prevent the dural tear was a simple departure from the standard of care.

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[14] Dr. Barry believed that Dr. Marino's conduct in the Susan K. procedure involved an extreme departure from the standard of care considered in its entirety; however, the allegations in the Accusation were "Respondent attempted a previously undocumented in the literature surgical approach on patient S.K." and "Respondent operated at the incorrect spinal level on patient S.K." Gross negligence was not alleged.

Dr. Marsolais testified a dural tear was quite common in spinal surgery, but severe injuries were uncommon. According to Dr. Marsolais, "[Dr. Marino] was protecting things as much as any of us could" during Kenneth D.'s procedure and, based upon Dr. Marino's description of the incident in a deposition, Dr. Marsolais concluded there was probably a "malfunction with the Stryker apparatus." However, Dr. Marsolais had not examined the Stryker device used in the Kenneth D. surgery and infrequently used a Stryker drill in his own practice. It was not established Dr. Marsolais specifically reviewed the design of the Stryker TPS drill to reach this conclusion.

The evidence established Dr. Marino used the Stryker drill and burr only because his favorite brand drill and bur was unavailable. Dr. Marino had actually used the Stryker drill and bur successfully for 10-20 minutes before it "suddenly" veered, which contradicted the notion that it was an inherently defective, out of control device. Dr. Marino did not claim the drill and burr was defective in his operative report or in his discharge summary, which one would have expected had a latent defect or a patently defective design been a significant contributing cause of an unexpected, debilitating injury. Dr. Marino's testimony that he suspected the ligamentum flavum was sufficiently robust to prevent the bur from penetrating it and going into the dura was mistaken, and it provided a sufficient factual basis to conclude that Dr. Marino failed to take sufficient precautions to avoid contact with that structure to the extent that was reasonably possible.

This evidence, taken together, established Dr. Marino's unreasonable failure to protect patient Kenneth D.'s ligamentum flavum and dura from trauma during surgery, a simple departure from the standard of care. Gross negligence was not established.

Credibility of the Experts

51. The physicians who testified as expert witnesses were highly trained, knowledgeable orthopaedic surgeons. Each expert witness based his opinion on essentially the same factual materials. Dr. Marino necessarily had more percipient information than the other experts, but unlike the other expert witnesses, Dr. Marino had a personal and professional stake in the outcome which skewed his perspective.

Dr. Barry proceeded from the unassailable position of "First do no harm." Based on this starting point and given the disastrous results of the three surgeries, Dr. Barry sometimes expressed a standard of care that was virtually synonymous with strict surgical liability, an untenable position. He was not particularly familiar with the legal standards concerning what kinds of conduct established gross negligence or constituted an extreme departure from the standard of care. There is no doubt that Dr. Barry is a highly skilled, very careful spinal surgeon who expects a great deal of himself and others.

Dr. Marsolais was at the other end of the forensic spectrum – he appeared to believe that simply because certain adverse surgical complications and results can occur (e.g., wrong level surgeries and dural tears during such surgeries), because a patient consents to surgery after being advised of a worse case scenario, and because the adverse outcomes involving the

patients in this matter fell into these areas, the surgical judgments and conduct giving rise to the allegations did not involve any violation of a standard of care. This perspective resulted in a far more tolerant view of the risks of spinal surgery than was necessary or appropriate. Further, it was hard to balance Dr. Marsolais' tolerance for Dr. Marino's conduct in the three surgeries with his eagerness to blame others - such as Dr. Peppers for performing an allegedly premature surgery and with Stryker for manufacturing a dangerous device – without concluding he was biased.

Dr. Marino had an excellent recollection of facts helpful to his defense, including his custom and practice. He was not as clear about those factual matters that were potentially unfavorable to his position. Dr. Marino testified about as honestly as possible for someone charged with unprofessional conduct, a highly stressful situation. His testimony was within factual bounds, but some of his judgments and conclusions were open to question. He did not falsify any records. Dr. Marino was candid and honest in his dealings with his patients after their surgical injuries. He is a very knowledgeable physician who remains current in his continuing professional education.

The clear and convincing evidence amply supported findings of Dr. Marino's simple departures from the standard of care in each of the three low back surgeries, but certainly not any finding of gross negligence or incompetence.

Disciplinary Guidelines

52. The Division of Medical Quality produced a Manual of Model Disciplinary Orders and Disciplinary Guidelines (9th Edition) for the use of those persons involved in the physician disciplinary process. The guidelines are not binding standards. A proposed decision departing from the disciplinary guidelines should identify the departures and the facts supporting the departures.

53. For unprofessional conduct involving repeated acts of negligence, a violation of Business and Professions Code section 2234, subdivision (c), the guidelines recommend the imposition of a maximum sanction of revocation and the imposition of a minimum sanction of revocation, stayed, with five years probation on appropriate terms and conditions.

Besides standard terms and conditions of probation, additional conditions of probation set forth in the guidelines include the completion of an educational course, a prescribing practices course, a medical record keeping course, an Ethics course, a clinical training program, as well as the passing of an oral or written competency examination, having a monitored practice, and a prohibition against a solo practice.

The Appropriate Measure of Discipline – A Departure from the Guidelines

54. The only area in which Dr. Marino poses any risk to the public is in the area of surgery, and even then the risk appears to be limited to keeping Dr. Marino from performing new, essentially untried surgical procedures based on the three simple acts of negligence.

However, Dr. Marino testified he stopped practicing surgery for, among other reasons, physical limitations associated with his post polio syndrome, and this self-disclosed limitation has been considered. While this self-policing certainly is commendable, it neither erases Dr. Marino's departures from the standard of care in three separate back surgeries nor guarantees that respondent would not, at some time in the future, choose to again practice surgery. Consequently, this limitation cannot serve as a substitute for discipline. . Additionally, if discipline could be avoided by the dismissal of an accusation by simply agreeing not to perform a certain act authorized by a duly issued certificate, public protection would suffer as subcategories of licensure would effectively be created without any explanation or justification and the agreement would not be enforceable.

It is true that Dr. Marino did not alter or falsify any patient records and he was candid and honest in his dealings with his patients and his colleagues. However, Dr. Marino did not disclose the experimental or novel nature of Ronald B's surgery and his relationship to the Nuvasive tools and procedures with patients Susan K. and Kenneth D. Under the circumstances, an Ethics course is indicated.

The protection afforded to the public by imposing discipline would be to :1) keep Dr. Marino from engaging in the kinds of experimental surgery that got him into this predicament, 2) keep him from performing any kind of surgery which he might be physically unable to perform, and 3) ensure there are adequate surgical safeguards in place The appropriate mechanism to accomplish these objectives is to revoke Dr. Marino's physician's and surgeon's certificate, stay the revocation, and impose a five (5) year probation with appropriate terms and conditions.

The Affirmative Defense of Laches

55. *Factual Matters: Ronald B.*: The surgery involving Ronald B. occurred on October 20, 2000. It resulted in the filing of a medical malpractice action in September 2001. The civil action was settled on November 7, 2002. On December 11, 2002, the Medical Board received the report of settlement.

Thereafter, outpatient records were obtained from Dr. Marino's civil attorney and copies of x-rays were obtained from Orthopaedic Surgery Associates of North County and Scripps Memorial Hospital. A neurosurgical consultant's report was prepared on November 10, 2003. In December 2003, the case was assigned to a Medical Board investigator, who obtained additional records and reports. In June 2004, a medical consultant reviewed the matter and recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated July 6, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared supplemental reports. In March 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

An Accusation was prepared, which was signed on April 28, 2005 and served on Dr. Marino thereafter. On June 23, 2005, the Office of the Attorney General filed a request to set an administrative Hearing with the Office of Administrative Hearings. It was determined the first dates both counsel had available for hearing commenced in mid-February 2006. A 10-day hearing was set to commence on February 13, 2006, with a prehearing conference and a settlement conference preceding that date. Due to a death in the family of one counsel, the hearing was continued by agreement to begin on April 4, 2006.

Susan K.: The surgery involving Susan K. occurred on January 19, 2001. It resulted in the filing of a medical malpractice action in November 2001, and the resolution of that action through an arbitration award in mid-December 2003.

On December 12, 2003, a Medical Board Investigator (who was investigating the matter involving Ronald B.) confirmed Susan K. had filed a malpractice action against Dr. Marino. On January 22, 2004, the Medical Board received a report of settlement. Thereafter, medical and hospital records and reports, as well as depositions, were obtained. In April 2004, a District Medical Consultant reviewed the matter and, following his review, he recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated June 29, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared a supplemental report. In April 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

The matter was prosecuted with the Ronald B. matter as set forth above.

Kenneth D.: The surgery involving Kenneth D. occurred on February 19, 2001. It resulted in the filing of a medical malpractice action in November 2001, and the settlement of that matter on April 15, 2002.

On May 14, 2002, the Medical Board received notice of the settlement. Records were obtained. In June 2002, those records were reviewed by a medical consultant who concluded there was a simple departure from the standard of care. The case was closed. In December 2003, the case was reopened and was assigned to a Medical Board investigator. Thereafter, medical and hospital records and reports, as well as depositions, were obtained. In April 2004, a District Medical Consultant reviewed the matter and, following his review, he recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated June 29, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared a supplemental report. In April 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

The matter was prosecuted with the Ronald B. matter and the Susan K. matter as set forth above.

Respondent's Contentions

56. Respondent contends the Accusation should be dismissed "due to the substantial and unreasonable length of time the subject matters have been investigated by the Medical Board before a formal accusation was filed" and due to "the prejudice of Dr. Marino's ability to meaningfully defend against the allegations made against him as the result of such delays.

Respondent argued the Ronald B. matter involved "an experimental surgery" for which "all necessary and appropriate consents were obtained," the Susan K. matter involved "an operation at the wrong level despite Dr. Marino's taking all reasonable intraoperative precautions," and the Kenneth D. matter involved "the malfunction of a surgical power bur manufactured by Stryker Instruments." Respondent claimed, "In the aggregate, the delay factors suggest that the Board unfairly and unreasonably sat on the investigation of the individual matters without regard to the potential prejudicial impact to Dr. Marino" and "due to the passage of time, some witnesses are no longer available" and those witnesses who were physically available suffered uncertain memories "due to the passage of time."

Respondent specifically claimed John Lauria, the Stryker representative to whom Dr. Marino spoke at a medical conference in San Francisco, was an important witness, possibly beyond the subpoena power of the administrative law judge, whose whereabouts were unknown. Respondent specifically claimed Robin Vaughan, M.D., a neurophysiologist, who monitored the procedure in the Barnett case, could not be located. Respondent claimed an inability to locate Katherine Kelley, R.N., an attending surgical nurse, who was deposed in the Dixon litigation. Respondent noted the memory of other witnesses had faded with time, as had Dr. Marino's.

Complainant's Contentions

57. Complainant contends the administrative law judge lacked jurisdiction to dismiss the Accusation under the Administrative Procedure Act, which contemplated the filing of a proposed decision subject to the agency's final determination. Complainant also contends respondent failed to establish either an unreasonable delay or, if he did, that such a delay resulted in prejudice to the respondent. Finally, complainant noted the Accusation was filed within the time permitted by Business and Professions Code section 2230.5.

Findings Concerning Unreasonable Delay and Prejudice

58. There were delays in the investigation of this matter. However, those delays were not necessarily unreasonable, and most causes for the delays were well explained in the Declaration of Nancy M. Edwards.

No witness was unable to testify effectively because of the passage of time. The witnesses in this matter testified competently, and in many instances their recollections were refreshed by depositions taken much earlier in the civil actions.

It was not established that any potential witness who was thought to be unavailable had relevant information sufficiently connected to the main issues in this proceeding to have changed the outcome. And, it was not established that a reasonably diligent effort was made to contact those persons.

There was no unreasonable delay in the prosecution of this matter.

Respondent did not meet his burden of establishing the elements of laches.

LEGAL CONCLUSIONS

The Standard of Proof

1. The standard of proof in an administrative disciplinary action seeking the suspension or revocation of a physician's and surgeon's certificate is "clear and convincing evidence." *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.

2. The key element of "clear convincing evidence" is that it must establish a high probability of the existence of the disputed facts, greater than proof by a preponderance of the evidence. Evidence of a charge is clear and convincing as long as there is a high probability that the charge is true. *People v. Mabini* (2001) 92 Cal.App.4th 654, 662.

3. "Clear and convincing evidence" requires a high probability. It must be so clear as to leave no substantial doubt and to command the unhesitating assent of every reasonable mind. See, *Mathieu v. Norrell Corp.* (2004) 115 Cal.App.4th 1174, 1190.

Purpose of Physician Discipline

4. The purpose of administrative discipline is not to punish, but to protect the public by eliminating those practitioners who are dishonest, immoral, disreputable or incompetent. *Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.

5. Business and Professions Code section 2229 provides in part:

"(a) Protection of the public shall be the highest priority for the Division of Medical Quality . . . and administrative law judges of the Medical Quality Hearing Panel in exercising their disciplinary authority.

(b) In exercising his or her disciplinary authority an administrative law judge of the Medical Quality Hearing Panel, the division . . . shall, wherever possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions as are indicated by the evidence.

(c) It is the intent of the Legislature that the division . . . and the enforcement program shall seek out those licensees who have demonstrated deficiencies in competency and then take those actions as are indicated, with priority given to those measures, including further education, restrictions from practice, or other means, that will remove those deficiencies. Where rehabilitation and protection are inconsistent, protection shall be paramount.

Business and Professions Code section 2234

6. Business and Professions Code section 2234 provides in part:

"The Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

. . .

(b) Gross negligence.

(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

(d) Incompetence . . ."

The Standard of Care

7. Physicians must exercise that degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession under similar circumstances. The standard of care is a matter peculiarly within the knowledge of experts; it presents the

basic issue and it can only be proved by expert testimony, unless the conduct required by the particular circumstances is within the common knowledge of the layman. *Williamson v. Prida* (1999) 75 Cal.App.4th 1417, 1424.

8. Expert opinion testimony is required to prove or disprove that the physician performed in accordance with the prevailing standard of care. *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 1001.

Negligence/Gross Negligence/Incompetence/Repeated Negligent Acts

9. "Negligence" is conduct falling below the standard of care. The standard of care varies in different situations, but the standard of conduct remains constant, i.e., due care commensurate with the risk posed taking into consideration all relevant circumstances. *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 997.

10. "Gross negligence" is "'the want of even scant care or an extreme departure from the ordinary standard of conduct.'" *Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.App.4th 1175, 1185-1186.

11. "Incompetence" is distinguished from simple negligence in that one may be competent or capable of performing a given duty, but negligent in performing it. A single negligent act is not equivalent to incompetence. *Kearl v. Board of Medical Quality Assurance* (1986) 189 Cal.App.3d 1040, 1054-1055.

12. By statute, "repeated negligent acts" requires two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care constitutes repeated negligent acts.

Cause Does Not Exist to Impose Discipline for Gross Negligence

13. Cause does not exist under Business and Professions Code section 2234, subdivision (b), to impose discipline against Dr. Marino's certificate for gross negligence. Gross negligence - the want of even scant care or an extreme departure from the ordinary standard of conduct – was not established by the clear and convincing evidence in relation to the surgeries involving Ronald B., Susan K., or Kenneth D.

This conclusion is based on factual findings 6, 11-17, 24-30, 35-42, 49-51 and on legal conclusions 1-3 and 6-10.

Cause Does Not Exist to Impose Discipline for Incompetence

14. Cause does not exist under Business and Professions Code section 2234, subdivision (d), to impose discipline against Dr. Marino's certificate for incompetence. Dr. Marino is a highly trained, highly qualified, competent orthopaedic surgeon. He possesses the education, training and skills required of an orthopaedic surgeon.

This conclusion is based on factual findings and on legal conclusions 1-6, 11-17, 24-30, 35-42, 49-51 and on legal conclusions 1-3, 6-8 and 11.

Cause Exists to Impose Discipline for Repeated Acts of Negligence

15. Cause exists under Business and Professions Code section 2234, subdivision (c), to impose discipline against Dr. Marino's certificate for repeated acts of negligence, but only if he intends to resume a surgical practice. The clear and convincing evidence established Dr. Marino committed three negligent acts or omissions. These acts did not arise out of a single negligent diagnosis. Each act or omission was a separate and distinct breach of the standard of care. In the surgery involving Ronald B., Dr. Marino violated the standard of care by allowing Ronald B. to remain in a prone operative position for 12 hours, a situation an ordinary, reasonable and prudent orthopaedic surgeon would have avoided under similar circumstances. In the surgery involving Susan K., Dr. Marino observed a disc which appeared inconsistent with the pathology that was shown in the pre-surgery imaging studies, but he continued to operate at the wrong L4-5 level rather than taking further reasonable action to confirm he was operating at the correct L5/S1 level, a simple departure from the standard of care. In the surgery involving Kenneth D., Dr. Marino engaged in a simple departure from the standard of care by using an unfamiliar high-speed bur in close proximity to the spinal cord and by failing to anticipate irregular movements of the device to avoid penetrating the ligamentum flavum and disrupting nerve roots in the cauda equina.

This conclusion is based on factual findings 6, 11-17, 24-30, 35-42, 49-51 and legal conclusions 1-3, 6-9 and 12.

The Affirmative Defense

16. Laches is an equitable defense which requires proof of both an unreasonable delay and prejudice resulting from that delay. The party asserting laches bears the burden of proof. Delay is not a bar unless it works to the disadvantage or prejudice of other parties. *Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 815.

17. Dr. Marino failed to establish any prejudice resulting from any unreasonable delay in the investigation and prosecution of this matter. Without that evidence, Dr. Marino did not establish an affirmative defense of laches.

This conclusion is based on factual findings 7 and 55-58 and on legal conclusion 16.

The Appropriate Measure of Discipline

18. The purpose of administrative discipline is not to punish, but to protect the public by eliminating practitioners who are dishonest, immoral, disreputable or incompetent. Protection of the public shall be the highest priority for the Division of Medical Quality and administrative law judges in exercising their disciplinary authority who must, wherever

possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions indicated by the evidence. Where rehabilitation and protection are inconsistent, protection shall be paramount.

The disciplinary guidelines are not binding standards. A proposed decision departing from the disciplinary guidelines should identify the departures and the facts supporting the departures.

The only area in which Dr. Marino poses any risk to the public is in the area of surgery, and even then the risk appears to be limited to keeping Dr. Marino from performing essentially untried surgical procedures, although Dr. Marino's admission that he stopped practicing surgery altogether for, among other reasons, physical limitations associated with his post polio syndrome, is relevant but not conclusive. The self-imposed moratorium on surgery does not erase the occurrence of the repeated negligent acts or respondent's failure to exercise proper judgment.

It is true that Dr. Marino did not alter or falsify any patient records and he was candid and honest in his dealings with his patients and his colleagues, but disclosure to Ronald B. of the novel surgical approach to be used and disclosure to patients Susan K. and Kenneth D of his interest in Nuvasive and the use of the tools and procedures he designed was warranted. Under the circumstances, an Ethics course is indicated.

The protection afforded to the public by imposing discipline is to:1) keep Dr. Marino from engaging in the kinds of experimental surgery that got him into this predicament, 2) keep him from performing any kind of surgery which he might be physically unable to perform, and 3) ensure there are adequate surgical safeguards in place. In addition, as public protection is the paramount function of the Division, the imposition of discipline and the concomitant creation of a public record would serve to notify an inquiring member of the public that these repeated negligent acts did in fact occur. Similarly, public policy is not served by the compartmentalization of the physician's and surgeon's certificate whereby a licensee can opt out of all formal discipline by simply agreeing not to perform any act authorized by the certificate. To have respondent simply agree not to perform surgery as a means of avoiding discipline places the Division in an untenable position: It must be hyper-vigilant to ensure that respondent is not performing surgery but leaves it without a means to verify that respondent is adhering to his agreement.

A probationary period with the attendant terms and conditions places the Division in a position to actually monitor respondent. Likewise, in the event that further discipline of respondent become necessary, this record of discipline may be used as a factor in aggravation.

ORDER

Physician's and Surgeon's Certificate No. G 40978 issued to respondent James Marino, M.D. is revoked; provided, however, the order of revocation is stayed and respondent is placed on five (5) years years probation on the following terms and conditions of probation.

1. *Clinical Training Program*

Within 90 days of the effective date of this decision, respondent shall submit to the Division or its designee for prior approval, a clinical training or educational program such as the Physician Assessment and Clinical Education Program (PACE) offered by the University of California - San Diego School of Medicine or equivalent program as approved by the Division or its designee. The exact number of hours and specific content of the program shall be determined by the Division or its designee, but the program shall be related specifically to respondent retraining himself in the field of surgery. Respondent shall successfully complete the clinical training program and he shall comply with the clinical training program recommendations and he may be required to pass an examination administered by the Division or its designee related to the program's contents. Respondent shall pay the costs of the clinical training program.

2. *Notification*

Within 15 days after the effective date of this decision, or at any time thereafter if he does not currently have staff privileges or membership, respondent shall provide the Division, or its designee, with proof of service that respondent has served a true copy of this decision on the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to respondent and at any other facility where respondent engages in the practice of medicine and on the Chief Executive Officer at every insurance carrier where malpractice insurance coverage is extended to respondent.

3. *Medical Evaluation and Treatment*

Respondent shall not engage in any kind of surgery until notified in writing by the Division or its designee of its determination that respondent is medically fit to practice surgery safely.

Within 30 calendar days of the effective date of this Decision, and on a periodic basis thereafter as may be required by the Division or its designee, respondent shall undergo a medical evaluation by a Division-appointed physician who shall consider any information provided by the Division or designee and any other information the evaluating physician deems relevant and shall furnish a medical report to the Division or its designee.

Following the evaluation, respondent shall comply with all restrictions or conditions recommended by the evaluating physician within 15 calendar days after being notified by the Division or its designee.

If respondent is required by the Division or its designee to undergo medical treatment, respondent shall within 30 calendar days of notice, submit to the Division or its designee for prior approval the name and qualifications of a treating physician of respondent's choice. Upon approval of the treating physician, respondent shall within 15 calendar days undertake medical treatment and shall continue such treatment until further notice from the Division or its designee.

The treating physician shall consider any information provided by the Division or its designee or any other information the treating physician may deem pertinent prior to commencement of treatment. Respondent shall direct the treating physician to submit quarterly reports to the Division or its designee indicating whether or not the respondent is capable of practicing surgery safely. Respondent shall provide the Division or its designee with any and all medical records pertaining to treatment that the Division or its designee deems necessary.

If, before the completion of probation, respondent is found to be physically incapable of resuming a surgical practice without restrictions, the Division shall retain continuing jurisdiction over respondent's license and the period of probation shall be extended until the Division determines that respondent is physically capable of resuming a surgical practice without restrictions. Respondent shall pay the cost of the medical evaluation(s) and treatment.

Respondent's failure to undergo and continue medical treatment or comply with the required additional conditions or restrictions is a violation of probation.

4. *Prohibited Practice*

During probation, respondent is prohibited from engaging in any kind of experimental or endoscopic surgery. Respondent shall not engage in any kind of surgery until notified in writing by the Division or its designee of its determination that respondent is medically fit to practice surgery safely and until he has taken and completed the clinical training program.

5. *Proctor Requirement*

Respondent shall be proctored for the first ten (10) surgeries performed by respondent in which respondent acts as the primary surgeon. Respondent shall notify the Division in writing upon the completion of the tenth surgery. No proctor is required if respondent is assisting in a surgery.

6. *Ethics Course*

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the Division or its designee. Failure to successfully complete the course during the first year of probation is a violation of probation.

An ethics course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Division or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Division or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Division or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

7. *Practice Monitor*

Within 30 calendar days of the effective date of this Decision, respondent shall submit to the Division or its designee for prior approval as a practice monitor(s), the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the Division, including but not limited to any form of bartering, shall be in respondent's field of practice, and must agree to serve as respondent's monitor. Respondent shall pay all monitoring costs.

The Division or its designee shall provide the approved monitor with copies of the Decision(s) and Accusation(s), and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision(s), Accusation(s), and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision(s) and Accusation(s), fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement.

Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

The monitor(s) shall submit a quarterly written report to the Division or its designee which includes an evaluation of respondent's performance, indicating whether respondent's practices are within the standards of practice of medicine or billing, or both, and whether respondent is practicing medicine safely, billing appropriately or both.

It shall be the sole responsibility of respondent to ensure that the monitor submits the quarterly written reports to the Division or its designee within 10 calendar days after the end of the preceding quarter.

If the monitor resigns or is no longer available, respondent shall, within 5 calendar days of such resignation or unavailability, submit to the Division or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If respondent fails to obtain approval of a replacement monitor within 60 days of the resignation or unavailability of the monitor, respondent shall be suspended from the practice of medicine until a replacement monitor is approved and prepared to assume immediate monitoring responsibility. Respondent shall cease the practice of medicine within 3 calendar days after being so notified by the Division or designee.

In lieu of a monitor, respondent may participate in a professional enhancement program equivalent to the one offered by the Physician Assessment and Clinical Education Program at the University of California, San Diego School of Medicine, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at respondent's expense during the term of probation.

Failure to maintain all records, or to make all appropriate records available for immediate inspection and copying on the premises, or to comply with this condition as outlined above is a violation of probation.

8. *Supervision of Physician Assistants*

During probation, respondent is prohibited from supervising physician assistants.

9. *Quarterly Declarations*

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Division, stating whether there has been compliance with all the conditions of probation. Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

10.. *Probation Unit Compliance*

Respondent shall comply with the Division's probation unit. Respondent shall, at all times, keep the Division informed of his business and residence addresses. Changes of addresses shall be immediately communicated in writing to the Division or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021(b).

Respondent shall not engage in the practice of medicine in respondent's place of residence. Respondent shall maintain a current and renewed California physician's and surgeon's license.

Respondent shall immediately inform the Division or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

11.. *Interview with the Division or Designee*

Respondent shall be available in person for interviews either at respondent's place of business or at the probation unit office, with the Division or its designee upon request at various intervals and either with or without prior notice throughout the term of probation.

12.. *Residing or Practicing Out-of-State*

In the event respondent leaved the State of California to reside or to practice elsewhere, respondent shall notify the Division or its designee in writing 30 calendar days prior to the dates of departure and return. Non-practice is defined as any period of time exceeding 30 calendar days in which respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program outside the State of California which has been approved by the Division or its designee shall be considered as time spent in the practice of medicine within the State. A Board-ordered suspension of practice shall not be considered as a period of non-practice. Periods of temporary or permanent residence or practice outside California will not apply to the reduction of the probationary term. Periods of temporary or permanent residence or practice outside California will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws and Probation Unit Compliance

Respondent's license shall be automatically cancelled if respondent's periods of temporary or permanent residence or practice outside California totals two years. However, respondent's license shall not be cancelled as long as respondent is residing

and practicing medicine in another state of the United States and is on active probation with the medical licensing authority of that state, in which case the two year period shall begin on the date probation is completed or terminated in that state.

13.. *Failure to Practice Medicine - California Resident*

In the event respondent resides in the State of California and if for any reason he stops practicing medicine in California, respondent shall notify the Division or its designee in writing within 30 calendar days prior to the dates of non-practice and return to practice. Any period of non- practice within California, as defined in this condition, will not apply to the reduction of the probationary term and does not relieve respondent of the responsibility to comply with the terms and conditions of probation. Non-practice is defined as any period of time exceeding thirty calendar days in which respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program which has been approved by the Division or its designee shall be considered time spent in the practice of medicine. For purposes of this condition, non-practice due to a Board-ordered suspension or in compliance with any other condition of probation, shall not be considered a period of non-practice.

Respondent's license shall be automatically cancelled if respondent resides in California and for a total of two years, fails to engage in California in any of the activities described in Business and Professions Code sections 2051 and 2052.

14.. *License Surrender*

Following the effective date of this Decision, if respondent ceases practicing due to retirement, health reasons or is otherwise unable to satisfy the terms and conditions of probation, respondent may request the voluntary surrender of his license. The Division reserves the right to evaluate respondent's request and to exercise its discretion whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, respondent shall within 15 calendar days deliver respondent's wallet and wall certificate to the Division or its designee and respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation and the surrender of respondent's license shall be deemed disciplinary action. If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

15.. *Probation Monitoring Costs*

Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Division, which may be adjusted on an annual

basis. Such costs shall be payable to the Medical Board of California and delivered to the Division or its designee no later than January 31 of each calendar year. Failure to pay costs within 30 calendar days of the due date is a violation of probation.

16. *Violation of Probation*

Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, the Division, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the Division shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

17.. *Completion of Probation*

Respondent shall comply with all financial obligations not later than 120 calendar days before the completion of probation. Upon completion successful of probation, respondent's certificate shall be fully restored.

18. Obey All Laws

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California, and he remain in full compliance with any court ordered criminal probation, payment obligations related to probation, and other probationary orders.

This decision shall become effective at 5:00 pm on the 5th day of January, 2007.

IT IS SO ORDERED this 6th day of December, 2006.

CESAR A. ARISTEIGUIETA, M.D.
Chairperson, Consolidated Panel
Division of Medical Quality
Medical Board of California

REDACTED

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	)	
	)	File No. 10-2002-141437
JAMES MARINO, M.D.	)	
	)	OAH No: L2005060740
Physician's and Surgeon's Certificate No. G-40978	)	
Respondent.	)	

ORDER GRANTING RECONSIDERATION

The proposed decision of the administrative law judge in the above captioned matter was adopted by the Board on June 7, 2006, and was to become effective on July 7, 2006. Petition for Reconsideration under Government Code Section 11521 was filed in a timely manner by Deputy Attorney General Steven Zeigen.

The petition for reconsideration having been read and considered, the Board hereby orders reconsideration. The Board itself will reconsider the case based upon the entire record of the proceeding, including the transcript. Both complainant and respondent will be afforded the opportunity to present written argument to the Board. You will be notified of the time for submitting written argument. In addition to written argument, oral argument may be scheduled if any party files with the Division, a written request for oral argument within 20 days from the date of this notice. If written request is filed, the Division will later serve all parties with written notice of the time, date and place of oral arguments.

Your right to argue any matter is not limited, however, no new evidence will be heard. The Division is particularly interested in the reconsideration of the penalty order.

The decision with an effective date of July 7, 2006 is stayed. This stay shall remain in effect until the Board issues its decision after reconsideration. For its own use, the Board has ordered a copy of the hearing transcript and exhibits. At your own expense, you may order a copy of the exhibits by contacting the transcript clerk at the Office of Administrative Hearings at:

Office of Administrative Hearings
320 West Fourth Street, 6th Floor, Suite 630
Los Angeles CA 90013
(213) 576-7200

To order a copy of the hearing transcript, please contact transcript clerk at:

Karen Napolitano, Transcript Coordinator
Kennedy Court Reporters, Inc.
(714) 835-0366

The address for serving written argument on the Board is:

Richard M. Acosta, Discipline Coordination Unit
Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento, CA 95825-3236

Please submit an original and 10 copies.

IT IS SO ORDERED this 28th of June, 2006.

A. Renee Threadgill
Interim Chief of Enforcement
Medical Board of California

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	)	
JAMES MARINO, M.D.	)	File No. 10-2002-141437
Physician's and Surgeon's Certificate No. G-40978	)	
Respondent	)	

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Division of Medical Quality of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on July 7, 2006.

IT IS SO ORDERED June 7, 2006.

MEDICAL BOARD OF CALIFORNIA

By: _____
Ronald L. Moy, M.D., Chair
Panel B
Division of Medical Quality

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: JAMES MARINO, M.D. Physician's and Surgeon's Certificate No. G 40978 Respondent.	Case Nos. 10-2002-141437; 10-2002-133773; 10-2003-153599 OAH No. L2005060740

PROPOSED DECISION

James Ahler, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on April 4-7 and 10-12, 2006, in San Diego, California.

Steven H. Zeigen, Deputy Attorney General, represented complainant David T. Thornton, the Executive Director of the Medical Board of California, State of California.

Michael J. Grace, Attorney at Law, represented respondent James Marino, M.D., who was present throughout the administrative proceeding.

On April 12, 2006, the matter was submitted.

ISSUES

Between June 2000 and February 2001, did Dr. Marino engage in gross negligence, repeated negligent acts, or demonstrate incompetence in connection with his care and treatment of three orthopedic patients?

If so, does cause exist to impose license discipline?

If so, what measure of license discipline should be imposed to protect the public?

Notwithstanding any discipline which might be otherwise be imposed in this matter, did complainant engage in an unreasonable delay in the investigation and prosecution of this matter causing prejudice to Dr. Marino to the extent that the Accusation should be dismissed on the grounds of laches?

FACTUAL FINDINGS

Dr. Marino's Background, Education and Training

1. James Marino, M.D. (Dr. Marino) was born in the Bronx, New York, on [redacted] He graduated from high school in 1972. He attended Tufts University, where he majored in Chemistry and Biology, receiving a Bachelor of Arts degree in 1975. Dr. Marino attended Howard University Medical School, where he participated in an accelerated honors program, graduating with a Medical Doctorate in 1978.

Dr. Marino completed a one-year surgical internship at the University of California, San Diego, School of Medicine in 1979. He completed a four-year orthopedic residency at the same institution in 1983.

Dr. Marino was board certified by the American Board of Orthopaedic Surgery in 1985. He is a member of the Western Orthopaedic Academy, the North American Spine Society, and the International Intradiscal Therapy Society. He is a Qualified Medical Evaluator with the State of California.

Dr. Marino held staff privileges at several San Diego County hospitals including Donald Sharp Memorial Hospital, Scripps Memorial Hospital and Pomerado Hospital. Dr. Marino's hospital staff privileges have never been revoked, although they are now inactive.

2. Dr. Marino entered private medical practice in the field of general orthopedic surgery in 1983. He initially had a solo practice with offices in the Mira Mesa and La Jolla areas. In 1996, Dr. Marino became associated with Orthopedic Surgery Associates of North County, a group of orthopedic surgeons with offices in Poway.

After moving his practice to Poway, Dr. Marino began specializing in lumbar spinal surgery; by 1998, his practice was limited to that subspecialty. Dr. Marino was the only full-time spine surgeon practicing out of Pomerado Hospital from 1998 through 2002.

3. In the mid-1990s, Dr. Marino became intrigued with the idea of performing lumbar spine surgery with endoscopic technology.[1] He visited Philadelphia, Pennsylvania, where he met with Parviz Kambin, M.D. (Dr. Kambin), whom Dr. Marino described as a pioneer in the field of endoscopic spinal surgery. Dr. Marino and approximately 40 other interested orthopedic surgeons spent a week with Dr. Kambin learning about endoscopic

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[1] An endoscope is a device with a light attached which is used to look inside the body. Endoscopes may be equipped with tiny surgical instruments. A medical procedure using any type of endoscope is called an endoscopy or endoscopic. For example, laparoscopic surgery involves an endoscope inserted through a small incision in the abdomen or chest, and is used as an alternative to traditional gall bladder and chest surgery; arthroscopic surgery is endoscopic surgery performed on joints such as the knee or shoulder.

spinal surgery. A part of the curriculum involved spending one morning and one afternoon working on cadavers under supervision.

From 1994 through 1996, Dr. Marino performed endoscopic percutaneous[2] discectomies in the care of eight to ten patients. According to Dr. Marino, he stopped performing these surgeries because they were, at the time, "unsettled and unreliable."

In 1997, Dr. Marino learned more about endoscopic percutaneous discectomies by attending the International Intradiscal Therapy Society's annual meeting. Dr. Marino joined the society. After 1997, Dr. Marino continued attending meetings, conferences and seminars involving minimally invasive spinal surgery, presenting poster and oral presentations at several conferences.

Before founding NuVasive, a medical device development company, Dr. Marino participated in a cadaver dissection at UCSD to learn more about minimally invasive spinal surgery with endoscopic techniques. In 1998, he spent three full days dissecting cadavers at conferences in Tennessee, Dallas and Chicago. By June 2000, and before the surgery involving patient Ronald B., Dr. Marino employed percutaneous endoscopic surgical techniques in the treatment of several patients with spinal problems. None of these procedures involved a transiliac approach through the psoas muscle.

4. In 1998, Dr. Marino founded NuVasive, a business venture engaged in the design, development and marketing of products used in the surgical treatment of spine disorders. When he was with NuVasive, Dr. Marino conceptualized and helped develop several devices including a surgical frame, a nerve avoidance system, and specialized surgical instruments. According to Dr. Marino, he consulted with many "world class spine surgeons" who visited the NuVasive headquarters in La Jolla.

Dr. Marino's relationship with NuVasive ended in 2002.

5. In November 2003, Dr. Marino discontinued his spinal surgery practice for two reasons. First, he was unable to stand comfortably for prolonged periods of time due to a post-polio syndrome. Second, as a result of three medical malpractice settlements, the high cost of malpractice insurance coverage made his surgical practice financially unrewarding.

Dr. Marino currently engages in a non-surgical clinical orthopedic medical practice. He has offices in La Jolla and Poway.

License History

6. On October 1, 1979, the Medical Board of California (the Medical Board) issued Physicians and Surgeon's Certificate No. G40978 to Dr. Marino.

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[2] "Percutaneous" means passed, done or effected through the unbroken skin.

There is no history of any discipline having been imposed against that certificate.

Jurisdictional Matters

7. On April 28, 2005, the Accusation was signed by complainant David T. Thornton, the Medical Board's Executive Director.

The Accusation alleged that in Dr. Marino' treatment of three patients – Ronald B., Susan K., and Kenneth D. – Dr. Marino engaged in gross negligence, committed repeated negligent acts, and demonstrated incompetence in connection with three low back surgeries from October 2000 through February 2001.

Dr. Marino, through counsel, denied the allegations and raised the affirmative defense of laches.

On April 4, 2006, the evidentiary record was opened. Jurisdictional documents were presented. Opening statements were given. On April 4-7 and 10-12, sworn testimony and documentary evidence was received. On April 12, closing arguments were given, the record was closed, and the matter was submitted.

Degenerative Disc Disease – Herniated Discs - Spinal Stenosis

8. *Degenerative disc disease.* The term "degenerative disc disease" describes normal changes in spinal discs associated with the aging process. Degenerative disc disease takes place throughout the spine; however, it most often involves the discs in the lower part of the cervical spine and the lumbar spine. A loss of fluid (known as desiccation) reduces the ability of the discs to act as shock absorbers, makes them less flexible and smaller, and narrows the distance between the vertebrae.

Disc herniation. A common cause of low back and radiating leg pain is a ruptured or herniated disc. With acute or repetitive trauma and/or desiccation, tiny tears or cracks form in the outer annulus or capsule of the disc. The nuclear material inside the disc may be forced out through the tears or cracks, causing the disc to bulge, extrude, rupture, or break into fragments. The presence of disc material outside its normal anatomical confines may compress the spinal cord and cause a variety of symptoms including dull or sharp pain, muscle spasm or cramping, radiating leg pain, leg weakness and/or loss of leg, ankle and foot functions. Sneezing, coughing, or bending may intensify the pain.

Spinal stenosis. Spinal stenosis involves the narrowing of the spinal canal - the open space in the spine surrounding the spinal cord. Spinal stenosis may be congenital or it may instead be the result of the degenerative process. With spinal stenosis, pressure can be placed on the spinal cord and on nerves where they exit vertebrae, leading to pain and possibly affecting nerve function. The symptoms of lumbar spinal stenosis are fairly

consistent: standing and walking become intolerable, even though sitting or driving a car may not cause any discomfort.

A variety of diagnostic techniques are used to diagnose degenerative disc disease, a herniated disc, and/or spinal stenosis, including x-rays, myleograms, discograms, CT scans, and MRI scans.

Conservative Treatment

9. Medical practitioners often use the term "conservative treatment" to describe any kind of therapeutic treatment for back problems that does not involve surgery including rest, medication, exercise, and physical therapy. If initial conservative measures fail, epidural steroid injections (nerve blocks) are sometimes administered.

Surgical Treatment

10. When all else fails, spinal surgery may be the only viable treatment option for a patient suffering from debilitating back pain caused by degenerative disc disease, a herniated disc, or spinal stenosis. There are a variety of surgeries and techniques to address all of these problems, some of which are described below.

Open Surgery: The classic surgical technique to treat a herniated disc is to perform a laminotomy and discectomy. This technique is performed by making an incision down the center of the back in the area above the herniated disc. Once the incision is made through the skin, the muscles are moved to the side, which enables the surgeon to visualize the back of the vertebrae. X-rays may be required during this part of the surgery to make sure that the correct vertebra has been exposed. A small opening is made between the vertebrae where the disc has extruded, ruptured, or fragmented, which allows the surgeon to see into the spinal canal. Once this is accomplished, the surgeon moves the nerve roots out of the way to see the intervertebral disc. The surgeon locates any disc material that has migrated into the spinal canal and removes it, with the goal of eliminating any pressure and irritation on the nerves of the spine. Using small instruments that fit inside the disc, the surgeon then removes as much of the remaining nuclear material inside the disc as possible to prevent it from extruding. After the procedure is completed, the muscles of the back are returned to their normal position around the spine. The skin incision is repaired with sutures or metal staples.

Foraminotomy: A foraminotomy is a surgical procedure performed to enlarge a foramina, the passageway where [through which?] a spinal nerve exits the spinal canal. During a foraminotomy, the spine surgeon removes any bone or tissue that obstructs the passageway and compresses the spinal nerve root, eliminating the source of the inflammation and pain.

Fusion: The most common reason for performing a spinal fusion is to alleviate low back pain related to painful motion of the vertebrae. The goal is to eliminate motion at a painful segment, thereby reducing the pain caused by the motion. The abnormal and painful

motion may be caused by painful discs (discogenic pain or degenerative disc disease), abnormal slippage of the vertebra (spondylolisthesis or spondylolysis), and/or other degenerative spinal conditions including but not limited to facet joint degeneration.

A spinal fusion may involve using a bone graft to cause two vertebral bodies to grow together into one long bone. Bone can be taken from the patient during the spinal fusion surgery (autograft bone), or it may be harvested from other sources (allograft bone). Fusion may also involve the use of specially designed surgical hardware including rods and screws.

Microdiscectomy: Within the past 20 years or so, vast improvements were made in the equipment available to spinal surgeons performing traditional laminotomies, discectomies, foraminotomies and/or spinal fusions. The microdiscectomy procedure is essentially the same as the classic, open surgical procedure described above, but it requires a much smaller incision. The advantage of microdiscectomy over the traditional approach is that a smaller incision results in less damage to the healthy parts of the spine during the operation, as well as a faster recovery period in most instances.

To see through the smaller incision, the surgeon uses an operating microscope or loupes. A small incision is made in the back just above the area where there is an anatomical problem capable of surgical correction. The muscles are moved aside and the vertebrae are visualized, the operation is performed in the same manner as in the open surgical approach described above. Intraoperative x-rays are often used to verify that the surgeon is operating on the disc that is causing the patient's symptoms.

Endoscopic Discectomy: Many surgical procedures were revolutionized by the development of surgical devices utilizing fiber optic light and miniature TV cameras (i.e., endoscopic devices). For example, torn cartilage in the knee is now routinely removed with the arthroscope, and gallbladders are routinely removed with the laparoscope. A similar approach may be evolving in the field of spinal surgery.

The notion is that if microdiscectomy does less damage because of a smaller incision, endoscopic discectomy might do even less damage than miscrodiscectomy because of an even smaller entry wound with a percutaneous incision. While endoscopic spinal surgical procedures appear to be evolving, they are not yet commonplace.

The endoscopic procedure proceeds on the same premise as the surgeries outlined above, but even smaller incisions (known as stab incisions) are made to access the body. A special magnified TV camera and very small surgical instruments are placed into the body through the incision and are ultimately directed into the spinal canal through the cannulas (a slender tube inserted into a body cavity or duct). The surgeon indirectly visualizes the operative field in carrying out the surgical procedures. Rather than looking directly at the spine as in the classic open surgery or in a microdiscectomy, the surgeon performing percutaneous endoscopic spinal surgery watches a TV screen. As the surgeon watches the screen, he or she directs specially designed instruments to remove disc material and to perform other surgical functions including fusions. The endoscopic procedure theoretically

involves less surgical trauma. Its drawback is that the surgeon does not directly see what he is doing. One of the promising features of the endoscopic techniques is the minimization of scarring around the nerves, a common cause of failure in open surgical procedures.

Surgical Complications: Well known surgical complications exist in any spinal surgery include anesthesia complications, blood clots, infections, and spinal cord injuries.

Patient Ronald B. - The Novel Transiliac Procedure

11. Ronald B. was born on [redacted]. He became a Senior Vice President with Arrowhead General Insurance and moved to San Diego.

12. Between February 3, 2000 and June 14, 2000, Ronald B. treated with Edward Venn-Watson, M.D. (Dr. Venn-Watson) for worsening bilateral, radiating low back pain. An MRI scan demonstrated a severe central spinal stenosis at L4-5, with a moderately severe encroachment narrowing both foramina and a bulging annulus on the right at L4-5. A course of conservative treatment, including a series of epidural steroid injections and physical therapy, failed. Dr. Venn-Watson referred Ronald B. to Dr. Marino.

13. Ronald B. first met with Dr. Marino on June 23, 2000. Ronald B. had been taking two to four Vicodin tablets daily for four or five months for pain. After a couple of visits, Ronald B. underwent a diagnostic procedure known as a lumbar discography. The results were consistent with severe concordant pain at L3-4 and L4-5 with evidence of disruption and annular tears. By then, Ronald B. was in severe pain. He was taking up to four Vicodin at a time and was barely able to stand.

14. On October 13, 2000, Dr. Marino discussed treatment alternatives with Ronald B., including conservative management (which had not been helpful) and surgery. With regard to surgery, Dr. Marino advised Ronald B. of the traditional surgical approaches and "a minimally invasive percutaneous approach." Dr. Marino told Ronald B. he had performed the proposed minimally invasive percutaneous approach on cadavers and baboons, but not on any living human patient. Dr. Marino told Ronald B. the minimally invasive surgery might last four to six hours.

It was not entirely clear if Dr. Marino said he would use an endoscopic surgical approach across the ilium and through the psoas muscle, a very novel medical procedure. Whatever Dr. Marino said, informed consent was not identified as an issue in the Accusation and it is of little importance here, except insofar as it was raised as a factual defense.

15. On October 13, 2000, Ronald B. signed a document entitled Research Subject Information and Consent Form. Ronald B. specifically consented to a procedure involving "intraoperative nerve surveillance in minimally invasive spinal decompression and fusion." Dr. Marino was described as the "investigator" and the study was sponsored by NuVasive, the company developing the nerve surveillance equipment.

The consent form stated the purpose of the research study was twofold: "first to determine whether adding several additional nerve-function tests to your surgical procedure can improve the outcome of your surgery; and second, to evaluate the effectiveness of an experimental (investigational) device in helping your surgeon perform these tests."

The consent form stated, "Because the study may require the surgeon to lengthen your surgery by approximately 5 to 15 minutes to permit placement of the extra electrode, your operative procure, and the length of your anesthesia, will be lengthened by this amount." The consent form also stated, "Other than the two types of nerve monitoring, your surgery will proceed exactly as it would if any were not participating in this research study." The consent form did *not* describe the surgical approach as being experimental or novel.

16. On October 20, 2000, at 6:15 a.m., Ronald B. signed another consent form related to a "lumbar fusion L3 L4 L5 with iliac bone graft" which was presented to him at the HealthSouth UTC Surgicenter immediately before surgery. Paragraph 3 of the HealthSouth consent form specifically mentioned possible complications including "nerve injury."

The consent forms did not purport to waive any act of negligence. The fact that Dr. Marino was engaged in a novel surgery involving an investigational protocol did not permit him to act in a manner inconsistent with existing standards of care.

17. After signing the final consent, Ronald B. was taken to the operating room. Brian Smith, M.D. (Dr. Smith) was the attending anesthesiologist.

The surgical plan was to remove disc material at L3-4 and L4-5 and to fuse the L3-4 and L4-5 vertebrae using endoscopic techniques. During surgery Ronald B. would be situated in the prone position on a padded Kambin surgical frame and his lumbar spine would be approached across the iliac crest through the psoas muscle with the use of a sterotactic guide (which Dr. Marino helped develop). Visualization would be accomplished using an image intensifier. A NuVasive INS-1 intraoperative nerve monitoring device (the subject of the WIRB investigational protocol) and a Viking Nicolete intraoperative nerve monitoring device (a predecessor device) were going to be used during the procedure to inform Dr. Marino if he was approaching vital nerves during surgery and to establish the fact of decompression of the nerve roots. Various NuVasive instruments, including specially designed cannulas, would be used during the procedure. Dr. Marino and other participants were required to wear a heavy lead shield during the procedure because of the radiation accompanying fluoroscopy.[3]

General anesthesia was administered at 7:10 a.m. The operative procedure began at 8:35 a.m. and it continued until 8:00 p.m. It took about six hours to perform the surgery at L3-4 and about another six hours to perform the surgery at L4-5. During those surgeries, Ronald B. remained immobile in the prone position. Between the surgeries, Ronald B. was

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[3] Fluoroscopy uses a continuous beam of X-rays to evaluate structures and movement within the body.

placed in reverse Trendelenburg position[4] for 20 minutes to optimize the flow of blood to the head. Anesthesia was discontinued at 8:27 p.m. There were numerous engineers and others from NuVasive present throughout the surgery.

According to Dr. Marino's testimony the surgery was very lengthy, but it went "spectacularly well." It took a long time for Dr. Marino to access the disc space with the transiliac approach and the removal of the disc material was incredibly slow because such small equipment was being used. Dr. Marino was not aware of any nerve injury occurring during the procedure. Dr. Marino's operative report, which was dictated immediately after the procedure, stated:

> "The patient tolerated the procedure well, was discharged to the recovery room with no more than approximately 500 cc blood loss . . ."

18. However, when Ronald B. tried stand up the next day, he unexpectedly experienced profound bilateral weakness in his lower extremities and could not do so. Ronald B. also suffered severe back discomfort.

19. Dr. Marino immediately had Ronald B. transferred from HealthSouth to Scripps Memorial Hospital, where Ronald B. was admitted on October 21, 2000 for a diagnostic evaluation and therapeutic treatment. Dr. Marino's admitting diagnosis was "Femoral nerve neuropraxia[5] secondary to surgical intervention."

On October 24, 2000, Ronald B. was discharged from the hospital and was transferred to a rehabilitation facility. Dr. Marino's discharge diagnosis was "Postoperative neuropraxia bilaterally femoral and obturator nerves." In the discharge summary, Dr. Marino wrote:

> "The patient is a 55-year-old-gentleman [who] sustained a neurologic deficit following an extended lumbar fusion procedure resulting in bilateral obturator and femoral nerve injuries . . ."

20. By letter dated February 20, 2001, Ronald B. formally discharged Dr. Marino as his treating physician, stating Dr. Timothy A. Peppers (Dr. Peppers) and Dr. Raymond J. Linovitz (Dr. Linovitz), each of whom was an orthopaedic surgeon specializing in spinal surgery, would assume the responsibility.

21. On April 16, 2001, Dr. Peppers, who was assisted by Dr. Linovitz, performed an anterior lumbar interbody fusion at L3-4 and L4-5 (removing the previous interbody

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[4] Trendelenburg's position is a position in which the patient is on an elevated and inclined plane, with the head down and legs and feet over the edge of the table. It is used in operations to push abdominal organs towards the chest. The reverse Trendelenberg position is self-explanatory.

[5] Neuropraxia is the physiological interruption of an anatomically intact nerve. In this condition there is minimal damage. The axons are intact but conduction is lost. It involves a transient lesion and recovery is spontaneous after a few days or weeks.

grafts), placed posterior spinal instrumentation from L3 through L5, performed a L4 laminectomy and a right-sided L3 hemilaminectomy for a "pseudoarthrosis, status post previous attempted L3-4 and L4-5 interbody fusion percutaneously" and a "post-laminectomy syndrome, lumbar spine, with right lower extremity neurologic deficit." The operative report stated preoperative imaging studies showed "evidence of pseudoarthrosis with nonhealing of the interbody grafts at L3-4 and L4-5." During the surgical procedure, motion was identified as the interbody grafts were removed.

Ronald B. was discharged from the rehabilitation facility on April 23, 2001, with a recommendation that he be followed by Robert Wailes, M.D. (Dr. Wailes), a pain specialist.

22. On January 28, 2002, Dr. Wailes inserted a spinal cord stimulator in Ronald B.'s spine to relieve pain arising from a "failed back syndrome."

23. In retrospect, it was concluded by virtually all the experts that Ronald B.'s neurologic injuries were likely secondary to stretching from his prolonged prone positioning during surgery and/or a neuropathy secondary to the insertion of cannulas through the psoas musculature. Ronald B. is presently on a daily regimen of 160 mg of OxyContin, 80 mg of Percocet, and 900 mg of Neurotonin. He has retired and lives in Texas.

Patient Susan K. – Wrong Level Surgery

24. Susan K. was born on [redacted]. After graduating from the University of California, San Diego, she married, had a daughter, and became employed as a software engineer.

Susan K. experienced low back problems in late 2000, which included radiating pain down her right leg. She was seen by several physicians. She was provided with conservative treatment including anti-inflammatory medications, epidural injections, and physical therapy. She came under the care of James M. Bried, M.D. (Dr. Bried). An MRI scan revealed the presence of a herniated and extruded disc pressing on the nerve root at L5/S1. When further conservative treatment failed to alleviate her symptoms, Dr. Bried referred Susan K. to Dr. Marino, his colleague.

25. Dr. Marino first met with Susan K. on January 9, 2001. He obtained a history of the present illness, a past medical history, performed a physical examination, reviewed the MRI scan (which he believed was consistent with a contained broad based disc protrusion at L5-S1, traversing the S1 nerve root), and spoke with Susan K. concerning her options. With regard to those treatment options, Dr. Marino's chart note stated:

> "We have presented the options of nonoperative as well as operative management, including a variety of operative treatments, such as hemilaminotomy, discectomy versus percutaneous lumbar discectomy. She has been apprised of the attendant risks and benefits, including the outcomes associated with each procedure and the

uncertainties associated with the percutaneous procedure and its lack of long-term follow-up studies in its current form.

Understanding these attendant risks and benefits, including infection recurrent disc herniation, nerve injury production persistent motor or sensory deficits, the patient has consented to percutaneous lumbar discectomy which will be arranged in the near future."

26. Susan K. recalled telling Dr. Marino that open back surgery "was not an option" because she considered it to be too invasive and too dangerous. She did not understand that it might be necessary to convert the percutaneous procedure to an open procedure, even though Dr. Marino was certain he explained that to her. She believed that while a nerve injury was possible, it was a very low risk.

27. Susan K. was admitted to Pomerado Hospital on January 10, 2001. She signed a consent to surgery which identified the following surgical procedure: "Percutaneous lumbar discectomy L5 S1, spinal monitoring."

The consent form also contained provisions indicating "All operations and procedures may involve risks of unsuccessful results, complications, injury, or even death, from both known and unforeseen causes . . ." The consent authorized Dr. Marino to perform the identified procedure and "any different or further procedures which, in the opinion of your supervising or attending physician or surgeon, may be indicated due to any emergency . . ."

Whatever Dr. Marino told Susan K., informed consent was not identified as an issue in the Accusation and it is of little importance here, except insofar as it was raised as a factual defense.

28. After signing the consent, Susan K. was taken to the operating room. Marc Zinser, M.D. (Dr. Zinser) was the attending anesthesiologist.

The surgical plan was to perform a discectomy and foraminotomy at L5/S1 using endoscopic techniques. During surgery Susan K. would be situated in the prone position on a Kambin frame and her lumbar spine would be approached across the iliac crest through the psoas muscle with the use of a sterotactic guide. Visualization would be accomplished with an image intensifier. A NuVasive INS-1 intraoperative nerve monitoring device would used during the procedure. NuVasive instruments, including cannulas, would be used during the percutaneous procedure. The procedure was very similar to the surgical approach involving Ronald B. less than six months before.

Anesthesia was administered at 8:55 a.m. The operative procedure began around 10:00 a.m. An effort was made to access to the L5/S1 interspace without having to remove any iliac bone, but that effort was thwarted by the presence of the iliac crest at its very upper margin. Efforts were then made to bore through the iliac crest, but that proved almost impossible. According to Dr. Marino's operative report, he decided after several attempts to

try to get the percutaneous instruments around the iliac crest, "this was not productive and [I] elected to proceed to an open hemilaminotomy disckectomy procedure."

According to the anesthesiologist's notes, a "decision to go to open case" was made at 11:55 a.m. Susan K. was prepared for the open surgery. There was not a medical emergency because without proceeding to an open procedure, there was no risk of life, limb or function.

According to the operative report, a midline incision was made at L5/S1, "confirmed our location with a standard lateral x-ray." Portions of the inferior lamina on the right side at L5 and the ligamentum flavum were removed and the spinal canal was opened. Bleeding was controlled. According to the report, the "traversing S1 nerve root was identified, retracted toward the midline and a small linear incision created in the annulus after which . . . rongeurs were used to remove disc material. A complete foraminotomy in the entrance zone of the foramen was created by using a power bur and Kerrison rongeur . . . . Intraoperative neuromonitoring showed considerable lowering of depolarization current threshold on the right side associated with both the L5 and S1 myotomes . . . [and after closing]. . . . The patient was discharged to the recovery room . . . without any overt complications."[6]

Surgery concluded at 2:12 p.m. Anesthesia was discontinued at 2:27 p.m.

29. When Dr. Marino met with Susan K. in the recovery room, he observed profound weakness and nerve loss in her right foot. He ordered a myelogram and CT scan.

30. The radiologist, Richard Price, M.D. (Dr. Price), spoke with Dr. Marino and said the images showed postoperative changes at L4-5, on the right, and a disc protrusion with a free fragment at L5/S1. Dr. Marino immediately reviewed the diagnostic images and concluded he had performed surgery at the wrong level.

31. Dr. Marino told Susan K. and her husband about the wrong level surgery. He told them the nerve monitoring equipment he had used (the NuVasive INS-1) gave him no indication of any nerve dysfunction at any time during surgery. He asked for permission to perform an open surgery to remove the herniation and fragment at L5/S1, believing the use of the fresh surgical track would minimize surgical trauma from a second surgery.

32. At 6:00 a.m. on January 11, 2001, Susan K. signed another consent, this time agreeing to a "fusion of L5-S1 with exploration & decompression of right L5 nerve root and iliac bone grafting." Thereafter, Susan K. withdrew her consent. She spoke with Marc Stern, M.D. (Dr. Stern), a neurosurgeon, to whom she was referred by Dr. Marino, and obtained a second opinion.

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[6] Dr. Marino later added a handwritten note to the operative report which stated:

"Post operative CT scan demonstrated inferior hemilaminotomy to have occurred at the right L-4 not right L-5 as was thought and intended."

33. Susan K. decided not to have additional surgery following her consultation with Dr. Stern. She was discharged from the hospital and remains under Dr. Stern's care. Her condition continues to improve slowly.

34. The defect at the L5/S1 level has never been surgically addressed. Susan K. has daily back pain with some radiation, for which she takes Vicodin and Motrin.

Patient Kenneth D. – The Dural Tear

35. Kenneth D. was born on [redacted]. After graduating from college, he was on active duty with the United States Marine Corps. Following his active duty, Kenneth D. became an executive officer with several high tech companies.

36. Kenneth D. experienced low back problems in 1999, including radiating pain down his left leg. Kenneth D. came under Dr. Bried's care.

X-rays revealed diffuse mild degenerative disc disease at L4-5 and L5-S1. An MRI scan revealed mild to moderate spinal stenosis. Kenneth D. obtained conservative treatment including rest, exercise, physical therapy, anti-inflammatory medications, and a series of epidural injections, but he remained quite symptomatic. On January 15, 2001, Dr. Bried referred Kenneth D. to Dr. Marino.

37. Kenneth D. first met with Dr. Marino on January 19, 2001. Dr. Marino took a history, performed a physical examination, reviewed x-rays and the MRI scan, and discussed treatment alternatives. According to Dr. Marino's chart note:

> "It's the patient's desire to proceed with hemilaminotomies to the left of midline at the L3-4 and L4-5 level. He's aware of the attendant risk and benefits including the potential for nerve injury, cerebral spinal fluid leakage, and persistent and/or recurrent pain."

38. Open spinal surgery was scheduled for February 19, 2001, at Pomerado Hospital. The proposed surgical procedures included bilateral hemilaminotomies and foraminotomies at the L3-4 and L4-5 levels.

39. On February 19, 2001, following his admission to Pomerado Hospital, Kenneth D. was taken to the operating room where he was anesthetized and intubated. He was placed in a kneeling position on an Andrews frame. A midline incision was made and the muscles and soft tissues over the operative site were retracted. The subcutaneous vessels were cauterized. A Kocher clamp was placed on the posterior portion of the vertebra at the L4 level to identify the dissection level. Dr. Marino removed disc material at that level, compressing the spinal cord and nerve roots.

During this portion of the procedure, Dr. Marino had been offered a rongeur (an instrument used to remove bone) that was too large for the task. When Dr. Marino asked for a rongeur more appropriate to the task, he was told one was not available. Dr. Marino then asked that one be obtained from a nearby hospital; in the interim, Dr. Marino decided to proceed with the surgery by using a smaller ronguer, which required him to use a power drill with a bur to thin the vertebrae. When Dr. Marino asked for an Anspach drill and bur, he was told it was unavailable, but he was told a Stryker TPS drill with bur was available. Dr. Marino had used that model drill and bur about half a dozen times before and he was somewhat familiar with it. He used the Stryker drill and bur for 10 to 20 minutes to thin the lamina at L4 without incident. According to his operative report:

> "Eventually ligamentum flavum was removed extending out into the foramen at the L4-5 level and with additional bone removed from the upper portion of the fifth lumbar vertebra."

Dr. Marino then turned his attention to the L3-4 level, where the power bur was used to remove bone. According to his operative report:

> "Unfortunately, even under careful visualization with use of a Fraser suction I encountered the dura, tearing it slightly, and causing small cerebrospinal fluid leakage. This was ultimately repaired with 6-0 Durelon to a watertight seal . . . I elected to use fibrin clot to reinforce the repair of the dura . . . by administering equal parts of cryoprecipiate and 10 percent calcium chloride solution with thrombin . . . A hemilaminotomy and foraminotomy was created to the right of the midline at the L4-5 level and also at the L3-4 level without incident. We had Valsalva maneuver performed on several occasions without evidence of any cerebrospinal fluid leakage. The wounds were closed after thorough irrigation with antibiotics over a drain the patient was discharged to the recovery room in good condition without apparent adverse consequence other than a single dural [tear] which was repaired."

The operative report did *not* mention the Stryker TPS drill and bur as being a contributory factor in causing the dural tear.

40. Dr. Marino testified that immediately before the dural tear, he was holding the Stryker device in his major/right hand, the Fraser suction device in his left hand. He was lightly "painting" the lamina of the L-3 vertebrae from the left side of the patient's body, removing bony material to access the disc. He thought he was in an area of safety. The bur was rotating at 50,000-60,000 rpm when it "moved violently" 1 to 2 cm to the right and contacted the ligamentum flavum, which wound around the bur and pulled the bur into the spinal canal. Before that occurred, Dr. Marino said he suspected the ligamentum flavum was sufficiently robust to prevent the bur from penetrating into the dura. When the bur engaged the ligamentum flavum, Dr. Marino immediately released the hand switch on the Stryker device, but he observed central spinal fluid leaking from a small tear in the dura, which he immediately attempted to repair.

41. That evening, Dr. Marino told Kenneth D. what had occurred. At the time, Kenneth D. had numbness in the left foot and weakness of the left ankle and foot. The next day, Kenneth D. had numbness in the scrotum and rectum with a weak anal sphincter tone. A CT myelogram revealed narrowing of the field and the cauda equina, particularly at the L3-4 level.

Dr. Marino thought there might be an external compression and performed a wound exploration on February 20, 2001. There was no evidence of a hematoma or compression phenomena on investigation.

42. On February 23, 2001, Dr. Marino dictated a discharge summary. In that report, he stated:

> "On the day of admission the patient underwent bilateral hemilaminotomy and foraminotomy procedures at the L3-4 and L4-5 levels. During the course of the procedure, an inadvertent dural laceration occurred with the power bur and the patent had a dural repair. Unfortunately, the patient woke up with significant deficits involving primarily his sacral nerve roots and also the left L-5, S1 motor and sensory areas. The deficits in the sacral region were not noted really until the first postoperative day. The patient had reported some scrotal numbness the evening of the procedure which I had originally attributed perhaps intraoperative positioning in this very obese gentleman, but later on examining the following day noted him to have loss of rectal tone and significant dense anesthesia in the perianal region."

The discharge summary stated Dr. James Nelson, a neurologist, concurred with Dr. Marino's diagnosis of bilateral lower and upper sacral nerve dysfunction, probably secondary to a cauda equina trauma resulting from the power bur intrusion into the intrathecal space.

Kenneth D. was transferred to a rehabilitation facility. Dr. Marino said he advised someone at Pomerado Hospital the drill might be defective.

43. Dr. Marino spoke with John Lauria (Lauria), a Stryker representative, at a medical conference in San Francisco and related his experience with the Stryker drill and bur. Dr. Marino said he was told there were "similar reports." Whether this was true is unknown. Lauria reportedly recommended Dr. Marino reverse the rotational direction of the drill when operating on the patient's left side. However, this reported recommendation did not make sense since the bur was designed to work when rotating in only one direction.

44. On April 9, 2001, Dr. Marino wrote a letter to Stryker. He described the incident involving Kenneth D. and the Stryker device, theorizing the "surgical mishap" was the result of a "potentially hazardous performance characteristic of the TPS instrument." He stated he had used the device properly and for its intended purpose. A copy of Dr. Marino's letter was directed to Lauria and another copy was directed to Pomerado Hospital's Surgical Department's supervisor. He received no response.

45. Dr. Marino followed Kenneth D. In a chart note dated May 11, Dr. Marino stated:

> "He and I discussed the possible contributory effects of various conditions during his surgical procedure. I related to him my concerns regarding my inability to restrain the caliber at the time it veered from the position in which I had it and its penetration into the ligamentum flavum."

46. Kenneth D. has no feeling in his left leg, but he taught himself how to balance himself on his feet. He starts bowel movements with his finger. He is incontinent of bladder and he wears diapers, which he changes three times a day. Kenneth D. remains employed in the computer industry.

Relevant Standards of Care

47. The "standard of care" requires a spinal surgeon to exercise that degree of skill, knowledge and care ordinarily possessed and exercised by other reasonably careful spinal surgeons in similar circumstances. The standard of care is a matter peculiarly within the knowledge of experts; it presents a basic issue which can only be established by expert testimony.[7]

Before discussing relevant standards of care, several matters should be noted.

First, the application of the legal doctrine of *res ipsa loquitur* ("the thing speaks for itself") does not apply. The medical procedures involved were not matters of common knowledge, and expert testimony was required to establish that Dr. Marino violated a standard of care, unless the common knowledge of laymen supported a finding of negligence (e.g., where the surgeon amputated the wrong leg, or where there was injury to a part of the body not within the operative field). "There is an element of drama and of the freakish and improbable in the typical *res ipsa loquitur* case."[8] A violation of a standard of care is not established because surgery was unsuccessful or because the surgeon made an error in judgment which was reasonable under the circumstances.[9]

Second, inferring negligence because an injury rarely occurs in a particular kind of surgery places an unfair burden on the medical profession and discourages the use of new procedures which may pose inherent risks even in the exercise of due care.[10]

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7 *Williams v. Prida* (1999) 75 Cal.App.4th 1417, 1424; *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 1001/

8 *Curtis v. Santa Clara Valley Medical Center* (2003) 110 Cal.App.4th 796, 801.

9 *Fraijo v. Hartland Hospital* (1979) 99 Cal.App.3d 331, 343.

10 *Curtis v. Santa Clara Valley Medical Center* (2003) 110 Cal.App.4th 796, 803.

Third, the standard of care does not fault a surgeon for choosing among different methods that have been approved by the profession, even if the choice later turns out to have been a wrong selection or one not favored by other members of the profession.[11]

Fourth, when a procedure inherently involves a known risk of death or serious bodily harm, the physician must disclose the possibility of such an outcome and explain it to the patient in lay terms.[12] However, obtaining a patient's informed consent to does not relieve a surgeon from exercising due care during the surgery.[13]

48. *Complainant's Expert Witnesses*

A. Raymond J. Linovitz (Dr. Linovitz): Dr. Linovitz is a highly trained, highly experienced orthopaedic surgeon specializing in spinal surgery. Dr. Linovitz did not provide expert testimony concerning relevant standards of care, but his percipient testimony as an experienced spinal surgeon established that a percutaneous endoscopic discectomy via a transiliac approach through the psoas musculature without direct visualization was so rare that he was unaware of such a procedure.

B. Richard J. Barry, M.D. (Dr. Barry): Dr. Barry received an undergraduate degree in Physical Sciences from San Jose State University in 1971. After graduating from college, Dr. Barry was on active duty as a commissioned officer with the United States Air Force. After completing pilot training, he served as a pilot in Vietnam and taught flying in Mississippi. Following his discharge from active military duty in the mid-1970s, Dr. Barry was admitted to the University of Mississippi, School of Medicine, where he received a Medical Degree with honors in 1980. Dr. Barry completed an orthopaedic residency at the University of Washington in Seattle in 1985.

Dr. Barry returned to active duty with the United States Air Force from 1985-1989, and became Chief of the Orthopaedic Clinic at Travis Air Force Base. He served as a senior aviation medical examiner for the FAA from 1981-1989.

Dr. Barry entered private practice in Davis, California, in 1989, with an orthopaedic medical group now known as Valley Oak Orthopaedics, where he remains. He serves as an unpaid Assistant Clinical Professor of Medicine with the University of California, Davis, School of Medicine, Department of Orthopaedic Surgery. Dr. Barry specializes in the treatment of spinal conditions, with a particular interest in spine microsurgery.

Dr. Barry was board certified by the American Board of Orthopaedic Surgery in 1986 and has since been recertified. In 1999, he was certified by the American Board of Spine

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11 *N.N.V. v. American Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1384.

12 *Mathis v. Morrissey* (1992)11 Cal.App.4th 332, 340.

13 See *Belshaw v. Feinstein* (1968) 258 Cal.App.2d 711, 726.

Surgery, a relatively new organization which was approved as a specialty certification board by the Medical Board in May 2002.

Dr. Barry is a fellow of the American College of Surgeons, the North American Spine Society, and the American Academy of Orthopaedic Surgeons. He is a member of the Board of Directors of the California Orthopaedic Association. Dr. Barry is on staff at local hospitals and surgery centers in the Sacramento area.

49. *Respondent's Expert Witnesses*:

A. Dr. Marino: Dr. Marino testified as both a percipient and expert witness. Dr. Marino's qualifications as an expert are set forth in factual findings 1-4.

B. Ernest B. Marsolais, M.D., Ph.D. (Dr. Marsolais): Dr. Marsolais received a Bachelor of Arts degree in General Science from the University of Iowa, Iowa City, Iowa, in 1960. He was admitted to the Medical University of Iowa and obtained a Medical Doctorate in 1953. He completed a general/plastic surgery internship at Columbia University, St. Luke's Hospital, in 1964.

Dr. Marsolais obtained a Master of Science degree in Engineering Mechanics from the Graduate University of Iowa, Dept of Mechanics and Hydraulics, in 1967, and a Ph.D. in Engineering Mechanics from that institution in 1969.

Dr. Marsolais completed an orthopedic surgery residency at the University of Iowa in 1970. He participated in an orthopaedic fellowship at the Wellesley Hospital in Toronto, Canada, in 1977-1978.

Dr. Marsolais holds memberships in the American Medical Association, the Iowa State Medical Society, the Iowa State Orthopaedic Society, the American Spinal Injury Association, the North American Spine Society, the Orthopaedic Rehabilitation Association, and the Orthopaedic Research Society.

Dr. Marsolais was on the faculty and taught orthopaedic surgery at Case Western Reserve University Medical School from 1970 until fairly recently. In 1990, he served as an adjunct associate professor of Biomedical Engineering, Case Western Reserve University.

Dr. Marsolais has authored numerous scholarly articles, including "Transforaminal and Posterior Decompressions of the Lumbar Spine: A Comparative Study of Stability and Intervertebral Foramen Area." That article was coauthored with several others and involved a study to determine the feasibility of an endoscopic transforaminal approach as an alternative to conventional approaches. The article appeared in *Spine* in August 1997.

50. *Ultimate Factual Conclusions*:

The following factual conclusions were fairly framed by the allegations set forth in the Accusation and were supported by the clear and convincing evidence after weighing all the conflicting expert testimony.

A. *Ronald B.*: Dr. Marino engaged in a simple departure from the standard of care in connection with Ronald B.'s low back surgery.

Dr. Marino allowed Ronald B. to remain in a prone operative position for 12 hours, a situation an ordinary, reasonable and prudent orthopaedic surgeon would have avoided under similar circumstances. The highly novel surgical approach Dr. Marino planned on using was theoretically sound, but it was practically unproven. Dr. Marino became aware very early in Ronald B.'s surgery that he could not proceed as quickly as he had hoped. As a surgeon, he should have been aware that Ronald B. would not benefit from a prolonged surgery and there were unjustified risks associated with an unnecessarily prolonged surgery. Dr. Marino's concerns in testing the INS-1 device and in completing a novel surgical procedure clouded his sound medical judgment and unreasonably interfered with what was in Ronald B.'s best surgical interest - the least traumatic, most prompt decompression and fusion of L3-4 and L4-5. Dr. Marino should have converted the unduly prolonged percutaneous, endoscopic procedure to an open procedure, as he did with patient Susan K.

Neurologic injuries can occur from stretching, bruising, or severing nerves. The standard of care requires a spine surgeon to take reasonable steps to ensure a patient does not sustain injury during a surgery. With regard to patient positioning, a spinal surgeon should be concerned whenever a surgical procedure lasts more than three hours and the patient remains prone and immobile. Dr. Barry's testimony established Ronald B.'s operative positioning for twelve hours - a result of Dr. Marino's use of the NuVasive investigational instrumentation and a "very aggressive posteriolateral approach" across the ilium and through the psoas musculature to reach the L3-4 and L4-L5 disc spaces - constituted a simple departure from the standard of care. A minidiscectomy could have been performed in less than half the time with a probability of a better result because the surgeon would not have to disrupt the psoas muscle and could have actually seen what he was doing. Dr. Marino obviously knew of the obligation to convert to an open procedure when it was in his patient's best interest, as he demonstrated in the Susan K. procedure.

Dr. Marsolais' testimony that there was nothing inherently wrong with Ronald B. being in the prone position for 12 hours - because Dr. Marsolais had participated in and knew of surgical procedures lasting that long or longer in which there was no patient harm, surgeries which had to last that long - did not establish a standard of reasonable care under the circumstances.

However, Ronald B.'s surgery did not involve an extreme departure from the standard of care simply because it was novel (as Dr. Barry conceded) or because the INS-1 device was

used (since it was used in conjunction with another proven and reliable nerve monitoring device). Dr. Marino provided Ronald B. with far more than scant medical care.

B. *Susan K.*: Dr. Marino engaged in a simple departure from the standard of care by performing a surgery at the wrong level and by inadvertently removing a healthy disc.

Wrong level disc surgery is not uncommon, but that does not mean that such surgery is reasonable or meets the standard of care. While Dr. Barry was not critical of Dr. Marino converting to an open surgical approach when he was unable to access patient Susan K.'s L-5/S-1 disc space through a percutaneous endoscopic approach, he was critical of Dr. Marino mistakenly operating at the L4-5 level when he observed a disc whose appearance was very inconsistent with the pathology that was shown in the pre-surgery imaging studies.[14] At that point, a reasonable and prudent spinal surgeon would not have simply assumed he was operating at the correct level and removed the disc; instead, the reasonable and prudent surgeon would have taken some further action to confirm he was at the correct level, such as requesting another intraoperative x-ray.

Gross negligence was not established.

Dr. Marsolais' testimony that he and all of his colleagues had engaged in wrong level disc surgery did not establish a standard of care, nor did his testimony about Dr. Marino's prudent conduct before the healthy disc was removed exonerate Dr. Marino from operating at the wrong level.

C. *Kenneth D.*: How careful should a spine surgeon be when he uses a drill with a bur that rotates at 50,000-60,000 rpm in close proximity to the spinal cord? According to Dr. Barry and Dr. Marsolais, the answer is very, very careful, because the risk of harm and the injuries resulting from a surgical misadventure can be so devastating.

Dr. Barry believed the standard of care required a spine surgeon using a high-speed power instrument, such as a drill and bur, to anticipate irregular movements of the device (i.e., "jumping" or "chattering") during surgery and to take precautions to avoid any injury if that should happen. Things do not always go smoothly and as planned during surgery. The surgeon should avoid penetrating structures such as the ligamentum flavum or disrupting nerve roots in the cauda equina. Dr. Barry believed Dr. Marino's failure to take adequate and reasonable precautions to prevent the dural tear was a simple departure from the standard of care.

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[14] Dr. Barry believed that Dr. Marino's conduct in the Susan K. procedure involved an extreme departure from the standard of care considered in its entirety; however, the allegations in the Accusation were "Respondent attempted a previously undocumented in the literature surgical approach on patient S.K." and "Respondent operated at the incorrect spinal level on patient S.K." Gross negligence was not alleged.

Dr. Marsolais testified a dural tear was quite common in spinal surgery, but severe injuries were uncommon. According to Dr. Marsolais, "[Dr. Marino] was protecting things as much as any of us could" during Kenneth D.'s procedure and, based upon Dr. Marino's description of the incident in a deposition, Dr. Marsolais concluded there was probably a "malfunction with the Stryker apparatus." However, Dr. Marsolais had not examined the Stryker device used in the Kenneth D. surgery and infrequently used a Stryker drill in his own practice. It was not established Dr. Marsolais specifically reviewed the design of the Stryker TPS drill to reach this conclusion.

The evidence established Dr. Marino used the Stryker drill and burr only because his favorite brand drill and bur was unavailable. Dr. Marino had actually used the Stryker drill and bur successfully for 10-20 minutes before it "suddenly" veered, which contradicted the notion that it was an inherently defective, out of control device. Dr. Marino did not claim the drill and burr was defective in his operative report or in his discharge summary, which one would have expected had a latent defect or a patently defective design been a significant contributing cause of an unexpected, debilitating injury. Dr. Marino's testimony that he suspected the ligamentum flavum was sufficiently robust to prevent the bur from penetrating it and going into the dura was mistaken, and it provided a sufficient factual basis to conclude that Dr. Marino failed to take sufficient precautions to avoid contact with that structure to the extent that was reasonably possible.

This evidence, taken together, established Dr. Marino's unreasonable failure to protect patient Kenneth D.'s ligamentum flavum and dura from trauma during surgery, a simple departure from the standard of care. Gross negligence was not established.

Credibility of the Experts

51. The physicians who testified as expert witnesses were highly trained, knowledgeable orthopaedic surgeons. Each expert witness based his opinion on essentially the same factual materials. Dr. Marino necessarily had more percipient information than the other experts, but unlike the other expert witnesses, Dr. Marino had a personal and professional stake in the outcome which skewed his perspective.

Dr. Barry proceeded from the unassailable position of "First do no harm." Based on this starting point and given the disastrous results of the three surgeries, Dr. Barry sometimes expressed a standard of care that was virtually synonymous with strict surgical liability, an untenable position. He was not particularly familiar with the legal standards concerning what kinds of conduct established gross negligence or constituted an extreme departure from the standard of care. There is no doubt that Dr. Barry is a highly skilled, very careful spinal surgeon who expects a great deal of himself and others.

Dr. Marsolais was at the other end of the forensic spectrum – he appeared to believe that simply because certain adverse surgical complications and results can occur (e.g., wrong level surgeries and dural tears during such surgeries), because a patient consents to surgery after being advised of a worse case scenario, and because the adverse outcomes involving the

patients in this matter fell into these areas, the surgical judgments and conduct giving rise to the allegations did not involve any violation of a standard of care. This perspective resulted in a far more tolerant view of the risks of spinal surgery than was necessary or appropriate. Further, it was hard to balance Dr. Marsolais' tolerance for Dr. Marino's conduct in the three surgeries with his eagerness to blame others - such as Dr. Peppers for performing an allegedly premature surgery and with Stryker for manufacturing a dangerous device – without concluding he was biased.

Dr. Marino had an excellent recollection of facts helpful to his defense, including his custom and practice. He was not as clear about those factual matters that were potentially unfavorable to his position. Dr. Marino testified about as honestly as possible for someone charged with unprofessional conduct, a highly stressful situation. His testimony was within factual bounds, but some of his judgments and conclusions were open to question. He did not falsify any records. Dr. Marino was candid and honest in his dealings with his patients after their surgical injuries. He is a very knowledgeable physician who remains current in his continuing professional education.

The clear and convincing evidence amply supported findings of Dr. Marino's simple departures from the standard of care in each of the three low back surgeries, but certainly not any finding of gross negligence or incompetence.

Disciplinary Guidelines

52. The Division of Medical Quality produced a Manual of Model Disciplinary Orders and Disciplinary Guidelines (9th Edition) for the use of those persons involved in the physician disciplinary process. The guidelines are not binding standards. A proposed decision departing from the disciplinary guidelines should identify the departures and the facts supporting the departures.

53. For unprofessional conduct involving repeated acts of negligence, a violation of Business and Professions Code section 2234, subdivision (c), the guidelines recommend the imposition of a maximum sanction of revocation and the imposition of a minimum sanction of revocation, stayed, with five years probation on appropriate terms and conditions.

Besides standard terms and conditions of probation, additional conditions of probation set forth in the guidelines include the completion of an educational course, a prescribing practices course, a medical record keeping course, an Ethics course, a clinical training program, as well as the passing of an oral or written competency examination, having a monitored practice, and a prohibition against a solo practice.

The Appropriate Measure of Discipline – A Departure from the Guidelines

54. The only area in which Dr. Marino poses any risk to the public is in the area of surgery, and even then the risk appears to be limited to keeping Dr. Marino from performing new, essential untried surgical procedures based on the three simple acts of negligence.

However, Dr. Marino testified he stopped practicing surgery for, among other reasons, physical limitations associated with his post polio syndrome, and this self-disclosed limitation has been considered. Dr. Marino does not need to complete additional educational courses, prescribing courses, medical record keeping courses or clinical training programs. He did not alter or falsify any patient records and he was candid and honest in his dealings with his patients and his colleagues. Under the circumstances, an Ethics course would not be indicated. The only protection afforded to the public by imposing discipline would be to keep Dr. Marino from engaging in the kinds of experimental surgery that got him into this predicament, and to keep him from performing any kind of surgery which he might be physically unable to perform.

If Dr. Marino intended to continue in a surgical practice, then cause would exist to impose a minimum period of probation, to require Dr. Marino to undergo a comprehensive physical examination to determine what kinds of surgery he could safely perform, and to require Dr. Marino to pass a surgical competency examination before returning a surgical practice (because he has not engaged in a surgical practice for more than three years), which would be limited only by his physical abilities. However, Dr. Marino has elected, at least for the time being, not to practice any kind of surgery – a decision based on physical limitations related to a post-polio syndrome and the high cost of medical malpractice insurance. Under these circumstances, and assuming these circumstances did not change, then cause would not exist to impose any discipline – it would simply be punitive, it would not serve to protect the public, and it would not function to rehabilitate Dr. Marino.

A concern would arise, however, if Dr. Marino changed his mind and decided to return to a surgical practice. To guard against that risk, a lengthy period of probation could be imposed with the condition that he not practice any surgery, but imposing such a disciplinary order would likely have the practical effect of terminating Dr. Marino's medical practice altogether since few insurance companies or governmental entities compensate a physician who is on probation for services rendered. This would be an unduly harsh result. In addition, the Board would be required to keep Dr. Marino on active probation, an unreasonable burden if he actually had no intention to return to surgery. Nevertheless, this kind of disciplinary order would be required in the absence of a clear, enforceable agreement between Dr. Marino and the Board concerning his surgical practice.

If Dr. Marino agreed in writing to give up his right to engage in any kind of surgery (both as the primary surgeon and as an assistant surgeon) and if he further agreed to the automatic suspension of his license if he were to engage in any kind of surgery, in consideration for the Medical Board's agreement not to impose formal discipline arising out of the Accusation filed in this matter, then cause would not exist to impose a disciplinary order. The public would be protected, the Board would not be required to monitor Dr. Marino for a lengthy period of probation, and Dr. Marino would not be restricted from engaging in a safe non-surgical medical practice.

An effort has been made to provide reasonable alternatives in the disciplinary order set forth herein.

The Affirmative Defense of Laches

55. *Factual Matters: Ronald B.*: The surgery involving Ronald B. occurred on October 20, 2000. It resulted in the filing of a medical malpractice action in September 2001. The civil action was settled on November 7, 2002. On December 11, 2002, the Medical Board received the report of settlement.

Thereafter, outpatient records were obtained from Dr. Marino's civil attorney and copies of x-rays were obtained from Orthopaedic Surgery Associates of North County and Scripps Memorial Hospital. A neurosurgical consultant's report was prepared on November 10, 2003. In December 2003, the case was assigned to a Medical Board investigator, who obtained additional records and reports. In June 2004, a medical consultant reviewed the matter and recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated July 6, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared supplemental reports. In March 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

An Accusation was prepared, which was signed on April 28, 2005 and served on Dr. Marino thereafter. On June 23, 2005, the Office of the Attorney General filed a request to set an administrative Hearing with the Office of Administrative Hearings. It was determined the first dates both counsel had available for hearing commenced in mid-February 2006. A 10-day hearing was set to commence on February 13, 2006, with a prehearing conference and a settlement conference preceding that date. Due to a death in the family of one counsel, the hearing was continued by agreement to begin on April 4, 2006.

Susan K.: The surgery involving Susan K. occurred on January 19, 2001. It resulted in the filing of a medical malpractice action in November 2001, and the resolution of that action through an arbitration award in mid-December 2003.

On December 12, 2003, a Medical Board Investigator (who was investigating the matter involving Ronald B.) confirmed Susan K. had filed a malpractice action against Dr. Marino. On January 22, 2004, the Medical Board received a report of settlement. Thereafter, medical and hospital records and reports, as well as depositions, were obtained. In April 2004, a District Medical Consultant reviewed the matter and, following his review, he recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated June 29, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared a supplemental report. In April 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

The matter was prosecuted with the Ronald B. matter as set forth above.

Kenneth D.: The surgery involving Kenneth D. occurred on February 19, 2001. It resulted in the filing of a medical malpractice action in November 2001, and the settlement of that matter on April 15, 2002.

On May 14, 2002, the Medical Board received notice of the settlement. Records were obtained. In June 2002, those records were reviewed by a medical consultant who concluded there was a simple departure from the standard of care. The case was closed. In December 2003, the case was reopened and was assigned to a Medical Board investigator. Thereafter, medical and hospital records and reports, as well as depositions, were obtained. In April 2004, a District Medical Consultant reviewed the matter and, following his review, he recommended an expert reviewer be obtained.

In late June 2004, the matter was referred to Dr. Barry, who issued a report dated June 29, 2004. In October 2004, Dr. Marino was interviewed at a Medical Board office. Portions of that interview were sent to Dr. Barry for review and comment, and Dr. Barry prepared a supplemental report. In April 2005, the matter was referred by complainant's investigators to the Office of the Attorney General.

The matter was prosecuted with the Ronald B. matter and the Susan K. matter as set forth above.

Respondent's Contentions

56. Respondent contends the Accusation should be dismissed "due to the substantial and unreasonable length of time the subject matters have been investigated by the Medical Board before a formal accusation was filed" and due to "the prejudice of Dr. Marino's ability to meaningfully defend against the allegations made against him as the result of such delays.

Respondent argued the Ronald B. matter involved "an experimental surgery" for which "all necessary and appropriate consents were obtained," the Susan K. matter involved "an operation at the wrong level despite Dr. Marino's taking all reasonable intraoperative precautions," and the Kenneth D. matter involved "the malfunction of a surgical power bur manufactured by Stryker Instruments." Respondent claimed, "In the aggregate, the delay factors suggest that the Board unfairly and unreasonably sat on the investigation of the individual matters without regard to the potential prejudicial impact to Dr. Marino" and "due to the passage of time, some witnesses are no longer available" and those witnesses who were physically available suffered uncertain memories "due to the passage of time."

Respondent specifically claimed John Lauria, the Stryker representative to whom Dr. Marino spoke at a medical conference in San Francisco, was an important witness, possibly beyond the subpoena power of the administrative law judge, whose whereabouts were

unknown. Respondent specifically claimed Robin Vaughan, M.D., a neurophysiologist, who monitored the procedure in the Barnett case, could not be located. Respondent claimed an inability to locate Katherine Kelley, R.N., an attending surgical nurse, who was deposed in the Dixon litigation. Respondent noted the memory of other witnesses had faded with time, as had Dr. Marino's.

Complainant's Contentions

57. Complainant contends the administrative law judge lacked jurisdiction to dismiss the Accusation under the Administrative Procedure Act, which contemplated the filing of a proposed decision subject to the agency's final determination. Complainant also contends respondent failed to establish either an unreasonable delay or, if he did, that such a delay resulted in prejudice to the respondent. Finally, complainant noted the Accusation was filed within the time permitted by Business and Professions Code section 22350.5.

Findings Concerning Unreasonable Delay and Prejudice

58. There were delays in the investigation of this matter. However, those delays were not necessarily unreasonable, and most causes for the delays were well explained in the Declaration of Nancy M. Edwards.

No witness was unable to testify effectively because of the passage of time. The witnesses in this matter testified competently, and in many instances their recollections were refreshed by depositions taken much earlier in the civil actions.

It was not established that any potential witness who was thought to be unavailable had relevant information sufficiently connected to the main issues in this proceeding to have changed the outcome. And, it was not established that a reasonably diligent effort was made to contact those persons.

There was no unreasonable delay in the prosecution of this matter.

Respondent did not meet his burden of establishing the elements of laches.

LEGAL CONCLUSIONS

The Standard of Proof

1. The standard of proof in an administrative disciplinary action seeking the suspension or revocation of a physician's and surgeon's certificate is "clear and convincing evidence." *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.

2. The key element of "clear convincing evidence" is that it must establish a high probability of the existence of the disputed facts, greater than proof by a preponderance of the evidence. Evidence of a charge is clear and convincing as long as there is a high probability that the charge is true. *People v. Mabini* (2001) 92 Cal.App.4th 654, 662.

3. "Clear and convincing evidence" requires a high probability. It must be so clear as to leave no substantial doubt and to command the unhesitating assent of every reasonable mind. See, *Mathieu v. Norrell Corp.* (2004) 115 Cal.App.4th 1174, 1190.

Purpose of Physician Discipline

4. The purpose of administrative discipline is not to punish, but to protect the public by eliminating those practitioners who are dishonest, immoral, disreputable or incompetent. *Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.

5. Business and Professions Code section 2229 provides in part:

"(a) Protection of the public shall be the highest priority for the Division of Medical Quality . . . and administrative law judges of the Medical Quality Hearing Panel in exercising their disciplinary authority.

(b) In exercising his or her disciplinary authority an administrative law judge of the Medical Quality Hearing Panel, the division . . . shall, wherever possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions as are indicated by the evidence.

(c) It is the intent of the Legislature that the division . . . and the enforcement program shall seek out those licensees who have demonstrated deficiencies in competency and then take those actions as are indicated, with priority given to those measures, including further education, restrictions from practice, or other means, that will remove those deficiencies. Where rehabilitation and protection are inconsistent, protection shall be paramount.

Business and Professions Code section 2234

6. Business and Professions Code section 2234 provides in part:

"The Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

. . .

(b) Gross negligence.

(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

(d) Incompetence . . ."

The Standard of Care

7. Physicians must exercise that degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession under similar circumstances. The standard of care is a matter peculiarly within the knowledge of experts; it presents the basic issue and it can only be proved by expert testimony, unless the conduct required by the particular circumstances is within the common knowledge of the layman. *Williamson v. Prida* (1999) 75 Cal.App.4th 1417, 1424.

8. Expert opinion testimony is required to prove or disprove that the physician performed in accordance with the prevailing standard of care. *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 1001.

Negligence/Gross Negligence/Incompetence/Repeated Negligent Acts

9. "Negligence" is conduct falling below the standard of care. The standard of care varies in different situations, but the standard of conduct remains constant, i.e., due care commensurate with the risk posed taking into consideration all relevant circumstances. *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 997.

10. "Gross negligence" is "'the want of even scant care or an extreme departure from the ordinary standard of conduct.'" *Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.App.4th 1175, 1185-1186.

11. "Incompetence" is distinguished from simple negligence in that one may be competent or capable of performing a given duty, but negligent in performing it. A single

negligent act is not equivalent to incompetence. *Kearl v. Board of Medical Quality Assurance* (1986) 189 Cal.App.3d 1040, 1054-1055.

12. By statute, "repeated negligent acts" requires two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care constitutes repeated negligent acts.

Cause Does Not Exist to Impose Discipline for Gross Negligence

13. Cause does not exist under Business and Professions Code section 2234, subdivision (b), to impose discipline against Dr. Marino's certificate for gross negligence. Gross negligence - the want of even scant care or an extreme departure from the ordinary standard of conduct – was not established by the clear and convincing evidence in relation to the surgeries involving Ronald B., Susan K., or Kenneth D.

This conclusion is based on factual findings 6, 11-17, 24-30, 35-42, 49-51 and on legal conclusions 1-3 and 6-10.

Cause Does Not Exist to Impose Discipline for Incompetence

14. Cause does not exist under Business and Professions Code section 2234, subdivision (d), to impose discipline against Dr. Marino's certificate for incompetence. Dr. Marino is a highly trained, highly qualified, competent orthopaedic surgeon. He possesses the education, training and skills required of an orthopaedic surgeon.

This conclusion is based on factual findings and on legal conclusions 1-6, 11-17, 24-30, 35-42, 49-51 and on legal conclusions 1-3, 6-8 and 11.

Cause Exists to Impose Discipline for Repeated Acts of Negligence

15. Cause exists under Business and Professions Code section 2234, subdivision (c), to impose discipline against Dr. Marino's certificate for repeated acts of negligence, but only if he intends to resume a surgical practice. The clear and convincing evidence established Dr. Marino committed three negligent acts or omissions. These acts did not arise out of a single negligent diagnosis. Each act or omission was a separate and distinct breach of the standard of care. In the surgery involving Ronald B., Dr. Marino violated the standard of care by allowing Ronald B. to remain in a prone operative position for 12 hours, a situation an ordinary, reasonable and prudent orthopaedic surgeon would have avoided under similar circumstances. In the surgery involving Susan K., Dr. Marino observed a disc which appeared inconsistent with the pathology that was shown in the pre-surgery imaging studies, but he continued to operate at the wrong L4-5 level rather than taking further reasonable action to confirm he was operating at the correct L5/S1 level, a simple departure from the standard of care. In the surgery involving Kenneth D., Dr. Marino engaged in a simple departure from the standard of care by using an unfamiliar high-speed bur in close proximity

to the spinal cord and by failing to anticipate irregular movements of the device to avoid penetrating the ligamentum flavum and disrupting nerve roots in the cauda equina.

This conclusion is based on factual findings 6, 11-17, 24-30, 35-42, 49-51 and legal conclusions 1-3, 6-9 and 12.

The Affirmative Defense

16. Laches is an equitable defense which requires proof of both an unreasonable delay and prejudice resulting from that delay. The party asserting laches bears the burden of proof. Delay is not a bar unless it works to the disadvantage or prejudice of other parties. *Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 815.

17. Dr. Marino failed to establish any prejudice resulting from any unreasonable delay in the investigation and prosecution of this matter. Without that evidence, Dr. Marino did not establish an affirmative defense of laches.

This conclusion is based on factual findings 7 and 55-58 and on legal conclusion 16.

The Appropriate Measure of Discipline

18. The purpose of administrative discipline is not to punish, but to protect the public by eliminating practitioners who are dishonest, immoral, disreputable or incompetent. Protection of the public shall be the highest priority for the Division of Medical Quality and administrative law judges in exercising their disciplinary authority who must, wherever possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions indicated by the evidence. Where rehabilitation and protection are inconsistent, protection shall be paramount.

The disciplinary guidelines are not binding standards. A proposed decision departing from the disciplinary guidelines should identify the departures and the facts supporting the departures.

The only area in which Dr. Marino poses any risk to the public is in the area of surgery, and even then the risk appears to be limited to keeping Dr. Marino from performing essentially untried surgical procedures, although Dr. Marino's admission that he stopped practicing surgery altogether for, among other reasons, physical limitations associated with his post polio syndrome, is relevant. Dr. Marino does not need to complete additional educational courses, prescribing courses, medical record keeping courses or clinical training programs. He did not alter or falsify any patient records and he was candid and honest in his dealings with his patients and his colleagues. Under the circumstances, an Ethics course would not be indicated. The only protection afforded to the public by imposing discipline would be to keep Dr. Marino from engaging in surgery until he establishes it is safe for him to practice surgery again. This may be unnecessary if Dr. Marino gives up his surgical

practice to avoid the imposition of formal discipline directed towards requiring him to abandon a surgical practice or, in the alternative, to engage in a surgical practice but only after he completes training required as a condition of probation. The disciplinary order set forth herein attempts to provide Dr. Marino and the Medical Board with these options.

ORDER

If respondent James Marino, M.D. files a signed agreement with the Medical Board of California in a form acceptable to the Medical Board in which respondent promises he will not practice or participate in any kind of surgery under Physician's and Surgeon's Certificate No. G 40978, then the Accusation shall be dismissed in lieu of the imposition of formal discipline. The agreement shall provide, in part, that respondent's certificate shall be automatically suspended if he engages in any kind of surgical practice pending a formal disciplinary hearing based on a violation of the agreement. The signed agreement must be submitted to the Medical Board before the effective date of the Decision herein

The following disciplinary order shall become effective upon the effective date of the Decision, but only if respondent James Marino, M.D. has failed or refused to file with the Medical Board of California a signed agreement in a form acceptable to the Medical Board in which he promises he will not practice or participate in any kind of surgery as a condition of continuing his practice without the imposition of formal discipline.

Physician's and Surgeon's Certificate No. G 40978 issued to respondent James Marino, M.D. is revoked; provided, however, the order of revocation is stayed and respondent is placed on ten (10) years probation on the following terms and conditions of probation.

1. *Obey All Laws*

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California, and he remain in full compliance with any court ordered criminal probation, payment obligations related to probation, and other probationary orders.

2. *Notification*

Within 15 days after the effective date of this decision, or at any time thereafter if he does not currently have staff privileges or membership, respondent shall provide the Division, or its designee, with proof of service that respondent has served a true copy of this decision on the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to respondent and at any other facility where respondent engages in the practice of medicine and on the Chief Executive Officer at every insurance carrier where malpractice insurance coverage is extended to respondent.

3. *Medical Evaluation and Treatment*

Respondent shall not engage in any kind of surgery until notified in writing by the Division or its designee of its determination that respondent is medically fit to practice surgery safely.

Within 30 calendar days of the effective date of this Decision, and on a periodic basis thereafter as may be required by the Division or its designee, respondent shall undergo a medical evaluation by a Division-appointed physician who shall consider any information provided by the Division or designee and any other information the evaluating physician deems relevant and shall furnish a medical report to the Division or its designee.

Following the evaluation, respondent shall comply with all restrictions or conditions recommended by the evaluating physician within 15 calendar days after being notified by the Division or its designee.

If respondent is required by the Division or its designee to undergo medical treatment, respondent shall within 30 calendar days of notice, submit to the Division or its designee for prior approval the name and qualifications of a treating physician of respondent's choice. Upon approval of the treating physician, respondent shall within 15 calendar days undertake medical treatment and shall continue such treatment until further notice from the Division or its designee.

The treating physician shall consider any information provided by the Division or its designee or any other information the treating physician may deem pertinent prior to commencement of treatment. Respondent shall direct the treating physician to submit quarterly reports to the Division or its designee indicating whether or not the respondent is capable of practicing surgery safely. Respondent shall provide the Division or its designee with any and all medical records pertaining to treatment that the Division or its designee deems necessary.

If, before the completion of probation, respondent is found to be physically incapable of resuming a surgical practice without restrictions, the Division shall retain continuing jurisdiction over respondent's license and the period of probation shall be extended until the Division determines that respondent is physically capable of resuming a surgical practice without restrictions. Respondent shall pay the cost of the medical evaluation(s) and treatment.

Respondent's failure to undergo and continue medical treatment or comply with the required additional conditions or restrictions is a violation of probation.

4. *Prohibited Practice*

During probation, respondent is prohibited from engaging in any kind of surgery until prior authorization is given by the Division. Respondent shall not engage in any kind of surgery until notified in writing by the Division or its designee of its determination that respondent is medically fit to practice surgery safely and until he has taken and completed the clinical training program.

5. *Clinical Training Program*

Within 90 days of the effective date of this decision, respondent shall submit to the Division or its designee for prior approval, a clinical training or educational program such as the Physician Assessment and Clinical Education Program (PACE) offered by the University of California - San Diego School of Medicine or equivalent program as approved by the Division or its designee. The exact number of hours and specific content of the program shall be determined by the Division or its designee, but the program shall be related specifically to respondent retraining himself in the field of surgery. Respondent shall successfully complete the clinical training program and he shall comply with the clinical training program recommendations and he may be required to pass an examination administered by the Division or its designee related to the program's contents. Respondent shall pay the costs of the clinical training program

6. *Supervision of Physician Assistants*

During probation, respondent is prohibited from supervising physician assistants.

7. *Quarterly Declarations*

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Division, stating whether there has been compliance with all the conditions of probation. Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

8. *Probation Unit Compliance*

Respondent shall comply with the Division's probation unit. Respondent shall, at all times, keep the Division informed of his business and residence addresses. Changes of addresses shall be immediately communicated in writing to the Division or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021(b).

Respondent shall not engage in the practice of medicine in respondent's place of residence.

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Respondent shall immediately inform the Division or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

9. *Interview with the Division or Designee*

Respondent shall be available in person for interviews either at respondent's place of business or at the probation unit office, with the Division or its designee upon request at various intervals and either with or without prior notice throughout the term of probation.

10. *Residing or Practicing Out-of-State*

In the event respondent leaved the State of California to reside or to practice elsewhere, respondent shall notify the Division or its designee in writing 30 calendar days prior to the dates of departure and return. Non-practice is defined as any period of time exceeding 30 calendar days in which respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program outside the State of California which has been approved by the Division or its designee shall be considered as time spent in the practice of medicine within the State. A Board-ordered suspension of practice shall not be considered as a period of non-practice. Periods of temporary or permanent residence or practice outside California will not apply to the reduction of the probationary term. Periods of temporary or permanent residence or practice outside California will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws and Probation Unit Compliance

Respondent's license shall be automatically cancelled if respondent's periods of temporary or permanent residence or practice outside California totals two years. However, respondent's license shall not be cancelled as long as respondent is residing and practicing medicine in another state of the United States and is on active probation with the medical licensing authority of that state, in which case the two year period shall begin on the date probation is completed or terminated in that state.

11. *Failure to Practice Medicine - California Resident*

In the event respondent resides in the State of California and if for any reason he stops practicing medicine in California, respondent shall notify the Division or its designee in writing within 30 calendar days prior to the dates of non-practice and return to practice. Any period of non- practice within California, as defined in this condition, will not apply to the reduction of the probationary term and does not relieve respondent of the responsibility to comply with the terms and conditions of probation. Non-practice is defined as any period of time exceeding thirty calendar days in which

respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program which has been approved by the Division or its designee shall be considered time spent in the practice of medicine. For purposes of this condition, non-practice due to a Board-ordered suspension or in compliance with any other condition of probation, shall not be considered a period of non-practice.

Respondent's license shall be automatically cancelled if respondent resides in California and for a total of two years, fails to engage in California in any of the activities described in Business and Professions Code sections 2051 and 2052.

12. *License Surrender*

Following the effective date of this Decision, if respondent ceases practicing due to retirement, health reasons or is otherwise unable to satisfy the terms and conditions of probation, respondent may request the voluntary surrender of his license. The Division reserves the right to evaluate respondent's request and to exercise its discretion whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, respondent shall within 15 calendar days deliver respondent's wallet and wall certificate to the Division or its designee and respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation and the surrender of respondent's license shall be deemed disciplinary action. If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

13. *Probation Monitoring Costs*

Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Division, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Division or its designee no later than January 31 of each calendar year. Failure to pay costs within 30 calendar days of the due date is a violation of probation.

14. *Violation of Probation*

Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, the Division, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the Division shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

15. *Completion of Probation*

Respondent shall comply with all financial obligations not later than 120 calendar days before the completion of probation. Upon completion successful of probation, respondent's certificate shall be fully restored.

DATED: May 11, 2006

JAMES AHLER
Administrative Law Judge
Office of Administrative Hearings

BILL LOCKYER, Attorney General
of the State of California
STEVEN H. ZEIGEN, State Bar No. 60225
Deputy Attorney General
California Department of Justice
110 West "A" Street, Suite 1100
San Diego, CA 92101

P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2074
Facsimile: (619) 645-2061

Attorneys for Complainant

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: JAMES MARINO, M.D. 9900 Genesee Avenue, Suite E La Jolla, CA 92037 Physician's and Surgeon's Certificate No. G40978 Respondent.	Case Nos. 10-2002-141437; 10-2002-133773; 10-2003-153599 OAH No. **ACCUSATION**

Complainant alleges:

PARTIES

1. David T. Thornton (Complainant) brings this Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs.

2. On or about October 1, 1979, the Medical Board of California issued Physician's and Surgeon's Certificate Number G40978 to JAMES MARINO, M.D. (Respondent). The Physician and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2007, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Division of Medical Quality (Division) for the Medical Board of California, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Division deems proper.

5. Section 2234 of the Code states:

"The Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

"(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter [Chapter 5, the Medical Practice Act].

"(b) Gross negligence.

"(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

"(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

"(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate

and distinct breach of the standard of care.

"(d) Incompetence.

"(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

"(f) Any action or conduct which would have warranted the denial of a certificate.

". . ."

6. Section 125.3 of the Code provides, in pertinent part, that the Division may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

7. Section 14124.12 of the Welfare and Institutions Code states, in pertinent part:

"(a) Upon receipt of written notice from the Medical Board of California, the Osteopathic Medical Board of California, or the Board of Dental Examiners of California, that a licensee's license has been placed on probation as a result of a disciplinary action, the department may not reimburse any Medi-Cal claim for the type of surgical service or invasive procedure that gave rise to the probation, including any dental surgery or invasive procedure, that was performed by the licensee on or after the effective date of probation and until the termination of all probationary terms and conditions or until the probationary period has ended, whichever occurs first. This section shall apply except in any case in which the relevant licensing board determines that compelling circumstances warrant the continued reimbursement during the probationary period of any Medi-Cal claim, including any claim for dental services, as so described. In such a case, the department shall continue to reimburse the licensee for all procedures, except for those invasive or surgical procedures for which the licensee was placed on probation."

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CAUSE FOR DISCIPLINE

(Gross Negligence, Repeated Negligent Acts, Incompetence)

8. Respondent is subject to disciplinary action under sections 2234 (b), (c), and (d) on account of the following:

Patient K.D.

A. Patient K.D. was a 50 year old male who presented to respondent for the first time on or about January 19, 2001, complaining of a six month pattern of pain in the left buttock and thigh, which the patient described as severe. An MRI of patient K.D. showed degenerative changes at the L4-5 and L5-S1 levels, with congenital stenosis at the L4-5 level. Respondent recommended L3-4 and L4-5 hemilaminectomies and foraminotomies.

B. Respondent admitted patient K.D. to Pomerado Hospital where he was taken to surgery on or about February 19, 2001. During the surgery respondent perforated the patient's dura with a high-speed bur, causing a dural tear and a leak of cerebral spinal fluid. This was repaired.

C. Postoperatively, the patient had an increased sensory loss of his lower left extremity, peroneal numbness, and decreased rectal sphincter tone. The patient underwent emergency CT myelography with findings of some compression of the thecal sac at the L3-4 level. Patient K.D. underwent another surgery on or about February 20, 2001, at which time some epidural fibrin glue was removed.

D. Following the second procedure the patient experienced bilateral lower extremity sacral nerve dysfunction. Patient K.D. was transferred to a rehabilitation center where an MRI on February 21, 2001, showed postoperative changes at the L3-4 and L4-5 levels.

E. In April and May 2001, patient K.D. continued to have loss of bowel and bladder function.

Patient R.B.

F. Patient R.B. was a 54 year old male patient who was referred to respondent in June 2000. An MRI showed the patient had severe compression of the nerve roots of the cauda equina at the L4-5 level. The patient had failed to respond to epidural steroid

injections and physical therapy.

G. On or about October 11, 2000, respondent performed a diskography which revealed symptomatic disk disease at the L3-4 and L4-5 levels.

H. On or about October 20, 2000, patient R.B. underwent a lumbar spine procedure consisting of a posterolateral retroperintoneal lumbar diskectomy, interbody fusion at L3-4 and L4-5, with facet joint screw fixation at L3-4 and L4-5 with iliac bone graft with neurologic monitoring. Both routine and experimental neurologic monitoring equipment were used. The procedures were performed in a prone position and took 12 hours.

I. Postoperatively, patient R.B. was unable to stand due to profound lower extremity weakness in the hip abductors and knee extensors. Patient R.B. was transferred to Scripps Memorial Hospital where CT myelogram and electrodiagnostic studies were performed. The consulting neurologist had the impression R.B. suffered from postoperative neurapraxia.

J. Patient R.B. changed physicians, and underwent a subsequent surgery by Dr. P. on or about April 16, 2001, with anterior interbody and classic posterolateral intertransverse lumbar fusions, with pedicle screw fixation.

Patient S.K.

K. Patient S.K. first saw respondent in early January 2001, after sustaining a lumbar spine injury in the fall of 2000. An MRI in December 2000 revealed a right-sided L5-S1 intervertebral disk herniation with displacement of the S1 nerve root.

L. Patient S.K. consented for respondent to perform a percutaneous lumbar diskectomy.

M. Respondent attempted a percutaneous posterolateral approach to the lumbosacral intervertebral joint but was unable to accomplish this given the patient's anatomy. Respondent attempted a previously un-described surgical procedure, boring through the iliac crest.

N. Respondent decided to convert the surgery to an open procedure on an emergency basis, proceeding with the more traditional open hemilaminectomy and disckectomy, procedures for which the patient had not consented.

O. Respondent performed the diskectomy at the incorrect level. Post operatively patient S.K. was found to have an L5 nerve root injury with a foot drop.

9. Respondent is subject to disciplinary action in that during his care, treatment, and management of patients K.D., R.B. and S.K., respondent was grossly negligent, committed repeated acts of negligence, and/or was incompetent by reason of, but not limited to, the following:

A. Respondent failed to protect patient K.D.'s dura from the power instruments used in the surgery.

B. Respondent allowed patient R.B. to remain in a prone operative position for 12 hours.

C. Respondent took a very aggressive posterolateral approach through the psoas muscle of patient R.B.

D. Respondent failed to take adequate precautions to protect patient R.B. from injury while using a previously undescribed and untried surgical procedure with a transiliac approach to the L4-5 intervertebral joint.

E. Respondent relied on an electrodiagnostic testing apparatus which had not been fully proven to be effective while operating on patient R.B..

F. Respondent attempted a previously undocumented in the literature surgical approach on patient S.K.

G. Respondent operated at the incorrect spinal level on patient S.K.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Division of Medical Quality issue a decision:

1. Revoking or suspending Physician and Surgeon's Certificate Number G40978, issued to JAMES MARINO, M.D..

2. Revoking, suspending or denying approval of James Marino, M.D.'s authority to supervise physician's assistants, pursuant to section 3527 of the Code;

3. Ordering James Marino, M.D., to pay the Division of Medical Quality the reasonable costs of the investigation and enforcement of this case, and, if placed on probation, the costs of probation monitoring;

4. Taking such other and further action as deemed necessary and proper.

DATED: April 28, 2005

DAVID T. THORNTON
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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